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Re: Wyeth case and failure to warn cases

RE: *Wyeth v. Levine* case (2009 WL 529172, US Supreme Court), which held that a drug manufacturer's warning on how to administer a drug was not adequate and affirmed a \$7 million verdict in favor of the plaintiff.

For the reasons below, I don't think the *Wyeth* case will have any relevance or applicability to WSTDA members. This is primarily for two reasons: 1) the labeling of drugs (including warning labels) is highly and strictly regulated by the Food and Drug Administration. There is also state regulation. No federal or state law regulates sling and tie down warning labels (in other words, a manufacturer does not have to submit its warning labels to a federal agency for approval; there is no federal agency that can order a sling manufacturer to word its warning labels in a certain way).

2) the issue in the *Wyeth* case was federal pre-emption: in other words, when a federal agency dictates what a manufacturer is supposed to do or not do, does the federal regulation take precedence over, or over-rule, state regulation on the same matter, such that if the manufacturer complies with federal law, it can ignore state law? Again, because our members are not regulated by the federal government or by the states the way drugs and drug manufacturers are, the federal pre-emption issue will not arise for us, at least not ordinarily.

In the *Wyeth* case, the plaintiff, a professional musician, sued Wyeth (plus the clinic and the clinician who administered the drug) for failure to warn of the dangers of administering a nausea medication directly into the patient's vein. She sued on a theory of negligence and strict liability: she said the labeling was defective because it failed to instruct clinicians to administer the drug in one way, and not another.

As a result of the way the drug was administered to her, the plaintiff developed gangrene and first her hand, then her whole forearm, had to be amputated. As a result, her career as a professional musician was ruined. A Vermont jury determined that the plaintiff's injury would not have occurred if the drug label included an adequate warning, and it awarded damages for her pain and suffering, substantial medical expenses, and loss of her livelihood as a professional musician. The courts rejected Wyeth's argument that the plaintiff's failure to warn claims were

pre-empted (overruled) by federal law because the drug's labeling had been approved by the federal Food and Drug Administration (FDA).

On these facts, the Supreme Court, in a 6-3 decision, held that the plaintiff's state law failure-to-warn claims against the manufacturer were not preempted by the Food, Drug and Cosmetic Act (FDCA). Further, the Court found that as a matter of fact, the manufacturer *could have* modified its warning label and could have complied both with state and federal law. Under the FDA's own regulations, Wyeth could have modified the label to "add or strengthen" a warning or to "add or strengthen an instruction about dosage" without waiting for FDA approval. It is a "central premise" of federal drug regulation that the drug manufacturer bears the responsibility for the content of its labels at all times. It is the manufacturer which is charged with the duty of "crafting an adequate label" and "ensuring that its warnings remain adequate as long as the drug is on the market."

This is a statement that would apply to sling manufacturers: That the manufacturer bears the responsibility for the content of its labels at all times and that it is the manufacturer's responsibility to "craft an adequate label" and "ensure that its warnings remain adequate" as long as the product is on the market. But this is exactly what WSTDA has always done and is doing now. So this doesn't change anything.

The above legal opinion was provided by Gerard Panaro, of Howe & Hutton, Washington, DC to the WSTDA Board of Directors.