

LAW REVIEW

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WYETH'S "GERD" DRUG DISCLAIMER RESULTS IN LAWSUIT

The drug manufacturer Wyeth produces the name-brand drug Reglan used to treat gastroesophageal reflux disease, also known as GERD, a condition I myself suffer. I also suffer high cholesterol and for that I take...oh forget it. Other less known manufacturers make generic versions of Reglan, which is actually metoclopramide. This 'case of first impression' arose concerning generic metoclopramide.

Wyeth Makes Reglan

For four years Plaintiff Elizabeth Conte took a generic prescription drug equivalent to Reglan. Conte developed a debilitating and incurable neurological disorder, which she attributed to taking the generic version of Reglan.

Drug Manufacturer Sued

Conte sued Wyeth claiming the company knew of a widespread tendency among physicians to mis-prescribe Reglan and generic metoclopramide for long periods of time even though the medication is only approved for 12 months of use—because the drug's labeling substantially understates the risks of serious side effects from extended use. I.e. Conte claimed Wyeth disseminated misleading and/or incomplete warnings about Reglan's side effects.

Wyeth defended Conte's suit alleging that her prescribing physician did not rely upon the Reglan warnings and product labeling, and a name-brand pharmaceutical manufacturer owes no duty to individuals who take only generic versions of its product.

The trial court ruled in favor of Wyeth. Conte appealed.

Conte alleged a name-brand manufacturer that disseminates information about its product owes a duty of care to ensure the information's accuracy to any doctor who prescribes the drug and relies on the information *even if* the patient ends up taking the name-brand product's generic equivalent. Amazingly, no court had ever looked at this issue in California before Conte's suit.

Just as interesting, under California law Wyeth's duty to warn of risks associated with its products runs to the physician, not the patient, so if someone is injured by a drug and claims lack of adequate disclosure of the potential dangers, it's not what they read about the drug that matters, it's what their prescribing physician reads. Wow. So it is immaterial if I buy a prescribed drug relying on misleading labeling by the manufacturer. That does not seem right.

Sad Digression

One of the leading cases in this area is *Motus v. Phizer*. Phizer makes the antidepressant Zoloft. Motus, like my younger brother, committed suicide a week or so after his physician prescribed an antidepressant—in his case Zoloft. My brother was given Effexor, also manufactured by Wyeth—prescribed to him by a general practitioner without any warning of the drug's known and well documented tendency to lead to an increased risk of suicidal behavior.

Victor Modus's widow sued Pfizer but lost because Victor's prescribing physician had not read the package insert or the Physician's Desk Reference information on Zoloft until after Victor died. Again, that makes no sense.

Generic Drugs

Under the Hatch-Waxman Amendments, a generic manufacturer is not required to submit evidence of the drug's safety, but instead need only certify that the generic product is the equivalent of the name-brand drug and that the labeling and the warning for the generic drug is the same as the name brand.

Court Ruling

The Court of Appeal concluded that Conte's physician was familiar with the Reglan warnings, and just because Wyeth did not manufacture or sell the generic version of its Reglan did not relieve the company from its obligation to disseminate accurate product warning labels. The Court wrote: "Wyeth owes a duty of due care to those people it should reasonably foresee are likely to ingest metoclopramide in either the name-brand or the generic version when it is prescribed by their physicians in reliance on Wyeth's representations (for the name-brand product)."

Wyeth's product representations regarding Reglan may be relied upon by consumers of its generic equivalent as long as the prescribing physician is familiar with the product labeling and relied upon the representations before the drug was prescribed.

I would not be surprised if this case is appealed to the California Supreme Court.

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