

Client Alert

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California Becomes First State to Recognize Innovator Liability**Areas of Interest****Product Liability /
Toxic Tort****United States**

On January 21, 2009, the California Supreme Court declined petitions to review the appellate court decision in *Conte v. Wyeth, Inc., et al.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008). In *Conte*, the appellate court held that Wyeth, a name brand manufacturer of Reglan® (a prescription drug used to treat gastroesophageal reflux disease), has a duty to warn patients whose doctors allegedly rely on Wyeth's labeling information for name brand

Reglan® when prescribing the drug, regardless of whether the patient's prescription is filled with the name brand drug or a generic version. In ruling this way, the court of appeals became the first court in the United States to recognize the so-called "innovator liability" theory of recovery.

Plaintiff alleged in *Conte* that she developed tardive dyskinesia after ingesting generic Reglan® for four years to treat her reflux disease. She further alleged that both Wyeth and certain generic-drug manufacturers could be held liable for her injuries because the warnings accompanying both the name brand and the generic products failed to adequately warn about the true risk of developing tardive dyskinesia beyond twelve weeks of therapy.

Because plaintiff had not ingested Wyeth's product, the Court of Appeal held that she could not assert traditional product liability claims against Wyeth. Nonetheless, the court held that plaintiff could assert a separate negligent misrepresentation claim against Wyeth. Rejecting the reasoning of every previous decision on the issue, the court stated:

The common law duty to use due care owed by a name-brand prescription drug manufacturer when providing product warnings extends not only to consumers of its own product, but also to those whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug.

By contrast, and notwithstanding evidence that the plaintiff ingested generic Reglan®, the *Conte* court dismissed all claims asserted against the generic manufacturers, including traditional products liability claims, because the evidence demonstrated that the plaintiff's physician did not rely on those manufacturers' labels in prescribing the generic product. Thus, under *Conte*, where a plaintiff can establish that a prescribing physician relied upon a branded manufacturer's label, liability can attach for alleged misrepresentations in that label even though the plaintiff suffered injury from ingestion of a generic product manufactured by another company.

Conte represents a potential sea change in products liability litigation. First, *Conte* departs from the leading case on innovator liability *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994) and the twenty-four courts in fourteen separate states that have followed the Fourth Circuit's decision. The *Foster* court concluded that misrepresentation claims asserted against a name manufacturer failed because: (i) the plaintiff did not ingest the name brand manufacturer's product; (ii) no FDA rule or regulation imposed liability on name brand manufacturers for injuries caused by generic manufacturers' products; and (iii)

imposing a duty to warn on the name brand manufacturer would stretch the concept of foreseeability too far.

Second, the *Conte* decision exposes brand name manufacturers to permanent and potentially boundless liability (at least in California) for injuries caused by their competitors' generic products. As just one example, a plaintiff may now be able to assert claims against a former name brand manufacturer, where the physician relied on that manufacturer's prior published label (which may not reflect current warnings or other information, and cannot be updated by the former manufacturer) in prescribing the generic product.

And third, the duty recognized in *Conte* threatens to create an insurance system under which name brand manufacturers absorb the liability of their competitors: competitors that, in many instances, not only enjoy greater market share, but are also relieved of research, development and advertising costs. This system, in turn, threatens to drive up the costs associated with the development and marketing of new drugs, which could chill innovation of new products and undermine the policy goal of preventing future injury to patients.

Notably, innovator liability is currently being considered by courts in a number of additional jurisdictions. In light of the appellate court decision in *Conte*, courts may now revisit the reasoning of prior, well-established holdings.

If you have any questions or require specific advice on any matter discussed in this Client Alert, please contact [Henninger S. Bullock](#) at +1 212 506 2528, [Andrew J. Calica](#) at +1 212 506 2256 or your regular Mayer Brown lawyer.

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