2024 Products Liability & Complex Torts Seminar

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A Duty to Innovate? An Untested Theory of Products Liability

California's Rulings in the Gilead Cases and their Wide Reaching Effect

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Gilead Case and its Ruling

California courts pave the way for radical expansion of liability for pharmaceutical manufacturers who delay in bringing new drugs to the market. *Gilead Sciences, Inc. v. Superior Court*, No. A165558, 2024 Cal. App. LEXIS 14, at *14 (Cal. Ct. App. Jan. 9, 2024) (review granted).[i]

Case Background

Defendant Gilead is a pharmaceutical manufacturer which developed and sold one of the first HIV/AIDS medications ("TDF"), approved by the FDA in 2001. TDF was effective in suppressing the effects of HIV although it carried a risk of side effects that include skeletal and kidney damage. A class of 24,000 consumers using TDF filed suit, alleging not that TDF was defective in any manner, but rather, that Gilead was negligent in not bringing an allegedly superior drug, TAF (with supposedly fewer side effects), to the market sooner.

Gilead had started clinical trials on TAF in approximately 2002, but elected to defer development of TAF for a period of time, eventually resuming development and receiving FDA approval in 2015. Plaintiffs contended that Gilead's decision to defer development of TAF breached its duty of reasonable care towards consumers. Gilead filed a motion for summary judgment arguing, in part, that plaintiffs seeking to recover for harm caused by a manufactured product must prove that the *product was defective*. The California superior court denied Gilead's motion and allowed the case to proceed.

On Appeal, California's Court of Appeals affirmed the trial court's denial of Gilead's motion for summary judgement reasoning that a manufacturer's duty to exercise reasonable care can extend to its decision to bring an alternative, allegedly safer drug, to market sooner. The court also adopted a theory that allows plaintiffs to assert a claim for negligence without proof of defect, at least as to decisions drug manufacturers make after obtaining results following Phase III clinical trials of an alternative drug.

While the ruling of the Court of Appeals was framed as "narrow", due to its potential to massively expand the liability of drug manufacturers, the California Supreme Court has granted review.

A multitude of governmental agencies, private companies (both drug manufacturers and others), individuals, and non-profits, have submitted amicus briefs in support of Gilead's position.

Potential for Wide Reaching Effects

- A theory of products liability which does not require a defect
- Potential to impact future innovation and drug manufacturing in a rule that encourages manufacturers to not invest in new developments
- Opens liability to manufacturers for undertaking research and expensive clinical trials.
- Changes the state of negligence and products liability law in California, as well as any other jurisdictions that follow suit.

[i] *Gilead Sciences, Inc. v. Superior Court*, No. A165558, 2024 Cal. App. LEXIS 14, at *14 (Cal. Ct. App. Jan. 9, 2024) (review granted).