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BLOG

Dozens of Amicus Filers in TDF Litigation Urge California Supreme Court Not to Uphold "Duty to Innovate"

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KEY TAKEAWAY

Amicus filings joined by more than 70 diverse entities ranging from manufacturers to patient advocacy groups highlight widespread concern that California courts will adopt an expansive new theory of liability based on a "duty to innovate" that filers say will upend existing products liability law, disincentivize innovation, increase drug prices, and harm patients.[1]

GILEAD LIFE SCIENCES

In May 2024, the California Supreme Court granted review of the appellate court's ruling in *Gilead Life Sciences, Inc. v. The Superior Court of the City and County of San Francisco*.[2] The courts below ruled that a pharmaceutical manufacturer could be liable to users of its drug by failing to bring a safer alternative to market sooner—a holding that sent shock waves through the pharmaceutical industry.

Previously, California courts generally found that drug manufacturers are not liable for plaintiffs' injuries if the drug was properly designed and manufactured, and the manufacturer properly warned about any side effects. In *Gilead*, however, the plaintiffs asserted that the pharmaceutical manufacturer Gilead was negligent, not because its HIV drug, tenofovir disoproxil fumarate (TDF), was defective or its side effects were not disclosed, but because Gilead allegedly delayed the development of a new drug with fewer side effects than TDF.

The lower courts allowed plaintiffs to proceed with the theory that Gilead was negligent solely because it delayed the development of an equally efficacious drug with fewer side effects. Thus, when the California Supreme Court reviews *Gilead*, it will determine whether pharmaceutical manufacturers are legally obligated to develop and bring to market a new drug if it would constitute an improvement over an existing drug. In other words, the Court will decide whether pharmaceutical manufacturers owe a duty to innovate.

EXEMPLARY AMICUS BRIEFS

Trade and Policy. A range of trade groups and research institutes filed briefs in support of reversal,[3] contending that a duty to innovate would unjustifiably depart from settled tort law and stifle the development of new medicines.

[4] The amici assert that the lower court's decision disregards the foundational rule that a plaintiff can only recover from a manufacturer upon proving that a defect caused an injury.[5] According to the amici, adopting a theory of negligence that does not require proof of a defect would disrupt the pharmaceutical industry, thereby undermining innovation and raising prices for consumers. Manufacturers necessarily weigh various factors to determine if the expected benefits of a potential new drug justify the costs and risks of its development and commercialization. The amici warn that a duty to innovate would mean that a manufacturer could face liability if it chooses not to develop a potentially safer new drug because the costs and risks associated with its development did not justify bringing it to market.[6]

Industry. Thirty-six manufacturers across the drug, medical device, automobile, and consumer goods industries argued that imposing a duty to innovate would upend research-and-development decision making to the detriment of consumers.[7] The manufacturers claim they will be disincentivized from researching improvements to existing products for fear that plaintiffs will allege improvements should have been made sooner. They also argue they will be incentivized to prioritize new products that are incremental improvements to existing products rather than dedicate resources to truly innovative products. Finally, they argue that the expansion of suits alleging breach of a duty to innovate will reduce the resources available to manufacturers to invest in innovation of any kind.

Patient Advocacy. Patient advocacy groups, including the HIV and Hepatitis Policy Institute and the Partnership to Fight Chronic Disease, also filed a letter brief in favor of reversal.[8] These amici emphasized that a duty to innovate discourages manufacturers from prioritizing research into treatments for rare medical conditions.[9]

Support for "Duty to Innovate." Four amicus briefs were filed in support of a duty to innovate on behalf of a non-profit legal public interest advocacy group, public health professors, and plaintiffs' bar associations. These amici argue that the oppositions' concerns about the fallout from the *Gilead* decision are overblown and that the real impact of the decision is to appropriately limit the ability of drug manufacturers to engage in market manipulation by delaying the launch of a new drug until it has maximized its profits from an older treatment.[10]

Responses to amicus briefs are due in late-January 2025. The California Supreme Court will likely set oral argument after responses are filed.

Law Clerk Bryn Hines also contributed to this blog post.

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[1] California Supreme Court, Docket for Gilead Tenfovir Cases, S283862

[2] *Gilead Life Scis., Inc. v. Superior Court of S.F.*, 320 Cal. Rptr. 3d 454, 546 P.3d 1114 (2024)https://www.gilead.com/tdf-litigation

[3] Brief for The Chamber of Commerce of The United States of America, The California Chamber of Commerce,

Washington Legal Foundation, and The National Retail Federation as Amici Curiae Supporting Petitioners, Gilead Tenofovir Cases, No. S283862 (Cal. Nov. 4, 2024).

[4] *Id.* at 8.

[5] *Id*. at 20.

[6] Brief for The International Center for Law and Economics as Amici Curiae Supporting Petitioners, Gilead Tenofovir Cases, No. S283862 (Cal. Nov. 4, 2024) at 21.

[7] Brief for Product Manufacturers and Affiliates as Amici Curiae Supporting Petitioners, Gilead Tenofovir Cases, No. S283862 (Cal. Nov. 4, 2024).

[8] Letter Brief for the HIV and Hepatitis Policy Institute and the Partnership to Fight Chronic Disease as Amici Curiae Supporting Petitioners, Gilead Tenofovir Cases, No. S283862 (Cal. Nov. 4, 2024).

[9] *Id*. at 5.

[10] Brief for Justice Catalyst, as Amici Curiae Supporting Respondents, Gilead Tenofovir Cases, No. S283862 (Cal. Nov. 4, 2024); Brief for American Association for Justice & Consumer Attorneys of California, as Amici Curiae Supporting Respondents, Gilead Tenofovir Cases, No. S283862 (Cal. Nov. 4, 2024).

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