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Appellate Reports

DUTY OF CARE IN DRUG DEVELOPMENT; ALSO, INSURANCE POLICY-LIMIT DEMANDS AND SUMMARY JUDGMENT

Negligence; duty of care; exception for manufacturer of non-defective drug to develop and commercialize an allegedly safer drug.

Gilead Tenofovir Cases (2026) 20 Cal.5th 390 (Cal. Supreme Court)

In the early 1990s, Gilead Sciences, Inc. (Gilead) obtained the rights to obtain approval to market tenofovir-based drugs to treat HIV. In 2001, it obtained regulatory approval of TDF, a tenofovir-based drug. A month after it obtained approval for TDF, Gilead began a small clinical trial of another Tenofovir-based anti-HIV drug called TAF. The study appeared to show that TAF had the same anti-viral properties as TDF, but at a significantly lower dosage, meaning that it posed considerably reduced risks of TDF side effects, such as kidney, bone, and tooth injuries.

Gilead announced in 2004 that it had ceased development of TAF, explaining that its safety, tolerability, and efficacy profile did not appear sufficiently different than TDF. Plaintiffs alleged that this explanation was pretextual, and that Gilead discontinued TAF development because it believed TAF could cannibalize TDF sales. Gilead resumed development of TAF in 2010, and ultimately obtained FDA approval for TAF in 2025.

Plaintiffs assert that this timing was deliberate, maintaining that Gilead waited until 2010 to resume TAF development to ensure that the drug reached the market in 2015 – just ahead of the expiration of Gilead’s TDF patent in 2017. According to plaintiffs, this strategy allowed Gilead to promote TAF as a safer, improved alternative, preserving a competitive advantage against generic versions of its TDF-based medications.

TDF-based medications remained on the market when Gilead commercialized

TAF in 2015, and they continue to be sold today. Plaintiffs do not contend that TDF is defective or that Gilead should have withdrawn it from the market. Indeed, plaintiffs acknowledged in the Court of Appeal that some patients prefer TDF over TAF. Instead, plaintiffs assert that Gilead unreasonably (negligently) delayed bringing TAF to market – which they believe could have been commercialized as early as 2006 – and that this delay deprived them, for many years, of the option to take what they allege is a safer drug. Plaintiffs allege that, as a result, they suffered serious renal, bone, or tooth injuries from taking TDF that could have been avoided had TAF been made available sooner.

Gilead moved for summary judgment of the plaintiffs’ two remaining claims for negligence and fraudulent concealment. The trial court denied the motion. Gilead petitioned for a writ of mandate, and the Court of Appeal ultimately granted the petition in part, directing the trial court grant summary adjudication as to the fraudulent-misrepresentation claim, but to deny it as to the negligence claim. The court reasoned that “the legal duty of a manufacturer to exercise reasonable care can, in appropriate circumstances, extend beyond the duty not to market a defective product.” The court further concluded that, on the record before it, the *Rowland* factors did not support recognizing an exception to the general duty of care.

The Supreme Court reversed. While it expressed general doubts about the viability of the plaintiffs’ claim, it ultimately resolved the issue based on application of the *Rowland* factors, which it concluded justified an exemption from the duty of ordinary care imposed by Civil Code section 1714.

With respect to the critical factor

of foreseeability, it found that the Court of Appeal erred in concluding that it is foreseeable that delaying the development and commercialization of a drug still in the early phases of clinical testing will harm users of an existing drug. Because a manufacturer cannot truly know of a drug’s safety and efficacy before phase III testing and FDA approval, it cannot reasonably foresee early in the development process that any delay in commercializing an alternative drug will harm users of an existing one. This factor therefore weighs in favor of recognizing an exception to any duty of care manufacturers might otherwise owe when developing and commercializing potentially safer alternative drugs.

On the issue of the closeness of the connection between the defendant’s conduct and the injury suffered, the Court concluded that a drug manufacturer’s decision to delay the commercialization of a new drug is, at most, only remotely connected to a plaintiff’s injury allegedly caused by use of an existing drug. Any such injury would depend on speculation regarding the independent conduct and discretionary decisions of multiple third-party actors, as well as the uncertain outcomes of additional clinical trials and scientific research required to develop, approve, and market the new drug.

With respect to the public-policy factors, the factor of “moral blame” is difficult to evaluate because drug manufacturers, as a class, may delay developing and commercializing an alternative drug for a variety of reasons. For example, a manufacturer might prioritize allocating its resources to developing a treatment for a disease or condition for which no therapies currently exist, rather than developing a safer therapy for a disease or condition already adequately treat-

ed by a nondefective drug. Or it might determine that, although an alternative drug presents a lower risk of certain rare but severe side effects, patients would not prefer it because it requires a complex dosing schedule or carries a higher risk of more common side effects. Or a manufacturer might conclude that any safety improvements are only marginal and that devoting resources to developing and commercializing the new drug would not be worthwhile, particularly where the existing drug was already meeting patient needs.

The second public-policy factor is “the policy of preventing future harm.” This policy is ordinarily served by imposing the costs of negligent conduct upon those responsible. But it may be outweighed by laws or mores indicating approval of the conduct or by the undesirable consequences of allowing potential liability. The plaintiffs concede that drug manufacturers already have ample incentives to release safer products into the marketplace, including the opportunity to gain market share and avoid reputational harm associated with adverse effects. This existing incentive structure lessens the need for tort liability as a means to ensure reasonable decisionmaking about whether and when to develop safer alternative drugs.

Perhaps more importantly, such a duty risks creating perverse incentives that may undermine, rather than advance, the goal of preventing future harm. Decisions regarding whether to continue developing a promising drug, how quickly to advance it through clinical trials, and how to allocate finite research and development resources are inherently complex. They rest on imperfect and evolving information, and often involve competing scientific, regulatory, and public-health considerations.

A duty to develop and commercialize, without undue delay, a potentially safer alternative to a nondefective drug could distort those decisions by encouraging manufacturers to prioritize incremental improvements to existing therapies at the expense of pursuing novel treatments

for diseases currently lacking effective treatments. A rational manufacturer could therefore conclude that investing additional resources in developing alternative drugs is necessary to reduce litigation risk, while research directed toward entirely new therapies carries no corresponding tort incentive.

Imposing the duty to develop new drugs on manufacturers would ultimately undermine public safety and could impose substantial burdens on drug manufacturers.

Accordingly, the *Rowland* factors counsel in favor of creating an exemption to drug manufacturers from the ordinary duty of care to users of a non-defective drug when making decisions about whether and when to commercialize an allegedly safer alternative drug.

Insurance; policy-limit demands; summary judgment

Farmers Ins. Exch. v. Superior Court (Wood) 122 Cal.App.5th 333 (Fourth Dist., Div. 1.) Doyle Archer was insured by petitioner Farmers Insurance Exchange (Farmers) when he rear-ended real party in interest Kathleen Ann Wood. Prior to litigation, Wood sent Farmers a policy-limit settlement offer that Farmers accepted within the time and in the manner required; Farmers also sent a copy of the requested declarations page. Wood refused to execute the settlement documents and initiated this action.

Separately, Farmers sued Wood for breach of contract, declaratory relief, and specific performance based on its acceptance of Wood’s settlement offer. The cases were consolidated. When the trial court denied Farmers’ motion for summary judgment, Farmers sought a writ. Granted.

On July 30, 2021, Wood’s attorney, Alderson, sent Farmers a letter offering to settle Wood’s personal injury claim against Archer for the “total available policy limit of \$100,000, or less,” if the offer was accepted in writing no later than 4:00 p.m. on August 30, 2021, and Farmers provided a copy of the declaration confirming the available policy limits.

The letter further states, “If this demand exceeds the policy, then we hereby make a policy limit demand.”

On August 25, 2021, Farmers sent a letter accepting Wood’s offer to resolve her personal injury claim against Archer for the policy limits of \$15,000.00. Farmers complied with all conditions set forth in Wood’s letter by (1) agreeing to pay the maximum policy limits available to her (\$15,000.00), and (2) providing the declaration pages that confirmed the available policy limit. Farmer’s letter provides: “As discussed, we are going to pay Kathleen Wood our single limit available \$15,000 for her injuries and the remaining \$15,000 will be distributed amongst [other pengers involved in the collision].”

After Farmers timely accepted Wood’s demand, by agreeing to pay the full “each person” policy limit and providing the policy’s declaration pages confirming the \$15,000.00 policy limit, Wood submitted, and Archer completed, an asset declaration indicating he owned one vehicle and had \$5,000 in the bank. However, an assets check identified other assets owned by Archer. In response, Wood refused to complete the prelitigation settlement documentation and on November 29, 2021, initiated an action against Archer. When Farmers’ meet and confer letter to enforce the settlement went unanswered, it sued Wood for breach of contract, declaratory relief, and specific performance.

A contract is formed when the parties mutually consent to lawful terms. Mutual assent usually is manifested by an offer communicated to the offeree and an acceptance communicated to the offeror. If there is no evidence establishing a manifestation of assent to the “same thing” by both parties, then there is no mutual consent to contract and no contract formation. The existence of mutual consent is determined by objective rather than subjective criteria, the test being what the outward manifestations of consent would lead a reasonable person to believe. It is enough that a reasonable person would understand that the parties consented to the contract and consented

to the same terms in the same sense.

The undisputed evidence demonstrates that: (1) Wood was represented by counsel; (2) Archer was represented by Farmers; (3) Wood is pursuing a claim for her bodily injuries arising out of the car accident; (4) on July 30, 2021, Wood's counsel mailed an offer to Farmers for the total available policy limit of \$100,000, or less/policy limits, in settlement of her claim against Archer; (5) on August 25, 2021, Farmers mailed Wood's counsel a letter tendering its global policy limits of \$30,000 (with no one person receiving more than \$15,000) and providing the documents requested by Wood's counsel. These communications evidence the parties' agreement that Farmers would pay Wood \$15,000 (its policy limits) in exchange for a full settlement of her bodily injury claim.

Wood argues if there was a contract, then Archer's assets declaration changed the terms, which he breached by failing to identify all of his assets, thus giving Wood "the right to rescind and pursue remedies in court as outlined in the terms." The court disagreed, explaining that Wood never made her offer contingent upon Archer's assets declaration. Contrary to Wood's assertion, Farmers' inclusion of such declaration did not equate to a novation or unwinding of the settlement. When parties agree on the material terms of a contract with the intention to later reduce it to a formal writing, failure to complete the formal writing does not negate the existence of the initial contract.

Since no triable issue of material fact exists regarding whether a binding settlement agreement was created on August 25, 2021, Farmers is entitled to summary

adjudication on its second cause of action for declaratory relief.



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