Gilead Tenofovir Cases

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WHY IT MADE THE LIST

Under traditional tort principles, if a manufacturer makes a prescription medication that is free from defects in its design, manufacture, and labeling, it should not be held liable for causing any warned-about side effects. In *Gilead Tenofovir Cases*,[1] the California Court of Appeal disagreed. There, the California Court of Appeal approved a novel theory of negligence liability based on the allegation that the pharmaceutical manufacturer knew that a *different* medication it invented to treat the same condition but which had not yet been approved by FDA had fewer side effects. Specifically, the court held that users of defendant Gilead's HIV/AIDS medication, tenofovir disoproxil fumarate (TDF), could assert a negligence claim—without proving any defect in TDF—based on Gilead's alleged decision to delay commercialization of a different medication, tenofovir alafenamide fumarate (TAF), once it allegedly acquired actual knowledge that TAF is safer than, and equally effective as, TDF.

Some believe *Gilead* will open the floodgates to lawsuits whenever a pharmaceutical manufacturer releases a new, improved medication. While those concerns are understandable, we believe *Gilead* is better read as an aberration from traditional tort principles that is limited to a particular set of facts. First, the court's finding of a duty of care is premised on a manufacturer having actual, rather than constructive, knowledge of a safer alternative medication. While the court did not slam the door on a constructive knowledge standard, it did signal skepticism. Second, Gilead and manufacturers in other cases may be able to significantly curtail potential liability if they can establish that such liability attaches only after the new, alternative medication has completed FDA Phase III clinical trials, which are designed to compare the safety and efficacy of a new medication to an existing one. Whatever the outcome, this case is one to watch.

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[1] 98 Cal. App. 5th 911 (2024).

THE FACTS

Gilead developed TDF as one of the first medications to treat HIV/AIDS.[2] While TDF is an effective treatment, as with any medication, it is not without risks. Accordingly, when FDA approved TDF in 2001, it did so with a label that warned about various side effects, including bone and kidney damage.[3] While Gilead was developing TDF, it discovered TAF, a similar, but chemically distinct, medication.[4] Plaintiffs allege that Gilead's early testing indicated preliminarily—but not definitively—that TAF might be as effective a treatment for HIV/AIDS as TDF but have fewer side effects than TDF. Gilead conducted Phase I and II clinical trials of TAF in 2002, but allegedly discontinued its development in 2004 to maximize TDF's profitability.[5] Gilead eventually resumed work on TAF in 2011, and conducted a Phase III study to compare TDF and TAF in 2013, which showed TAF had less impact than TDF on bone metabolism and kidney function.[6] FDA approved TAF in 2015.[7]

Over 24,000 TDF users sued Gilead in California state court.[8] While they originally filed claims for strict product liability, negligence, breach of warranty, and fraudulent concealment, plaintiffs ultimately dropped any claim that TDF is defective as designed and narrowed their case to two theories: 1) Gilead failed to disclose facts relating to TAF while it was under development; and 2) Gilead breached its duty of reasonable care by postponing TAF's development in 2004 despite knowing TAF is a safer alternative to TDF, thus depriving plaintiffs of the *choice* between TDF and TAF.[9]

Gilead moved for summary judgment on each of plaintiffs' remaining claims. Although Gilead disputed plaintiffs' assertions about its knowledge of the relative safety and efficacy of TAF as well as its alleged profit motives for "delaying" commercialization, its motion focused on threshold legal issues and not the factual disputes. As to the fraudulent concealment claim, Gilead argued "it had no duty to disclose facts relating to TAF when it had not been approved as an alternative to TDF."[10] As to plaintiffs' negligence claim, it argued there can be no such claim without proof of a defect. "The trial court denied the motion in its entirety."[11]

Gilead filed a writ petition in 2022 presenting two questions. First, as to fraudulent concealment, Gilead asked whether it had a duty "to disclose facts relating to TAF, which was not available as an alternative to TDF."[12] Second, for negligence, the question presented was "whether a drug manufacturer, having invented what it knows is a safer, and at least equally effective, alternative to a prescription drug that it is currently selling and that is not shown to be defective, has a duty of reasonable care to

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2 *Id.* at 916.

3 *Id.* at 918.

4 *Id.* at 916.

5 *Id.* at 918.

6 *Id.* at 919 n.1.

7 *Id.* at 916.

8 *Id.*

9 *Id.* at 919.

10 *Id.* at 917.

11 *Id.*

12 *Id.* at 948.

users of the current drug when making decisions about the commercialization of the alternative drug."[13]

ANALYSIS AND HOLDING

The court granted the writ as to the fraudulent concealment claim, agreeing that Gilead had no duty to disclose facts about a potential alternative product that was not yet available for use. According to the court, "information about a [medication] that was not available, and ***could not possibly*** become available as a treatment for many years as a result of the time-consuming FDA approval process, would not have been material" to patients deciding whether to take TDF.[14] In other words, the court recognized that it would be "irrational" to make treatment decisions based on a product that might never come to be.[15]

Yet, paradoxically, the court found that Gilead ***did*** have a duty to bring TAF to market without delay. In arguing before the Court of Appeal, Gilead focused on plaintiffs' decision to abandon any claim that TDF is defectively designed. According to Gilead, because a manufacturer satisfies its duty of reasonable care by making a product that is not defective, plaintiffs' abandonment was fatal to its negligence case.[16] While that argument has obvious appeal given the history of product liability, the court did not agree. After reviewing a series of California cases, the court concluded that while proof of product defect may be necessary for a strict liability claim, it is not for negligence.[17] "Rather, the critical question for plaintiffs' purposes is simply whether Gilead's years-long delay in bringing TAF to market, despite knowing its equivalent efficacy to TDF, breached a duty of reasonable care to users of TDF if the reason was solely to maximize Gilead's profits."[18]

Having concluded that plaintiffs did not need to prove a design defect, the court analyzed plaintiffs' theory of liability under California's duty of care statute, Civil Code 1714(a), which imposes a general duty of "ordinary care or skill in the management of [] property or person." It held that Gilead bore the burden of showing that the *Rowland* factors—a set of foreseeability and public policy factors stemming from *Rowland v. Christian*, 69 Cal. 2d 108 (1968)—justified an ***exception*** to its duty of care. Although Gilead disputed plaintiffs' allegations, the court accepted—for purposes of its analysis—that Gilead both had actual knowledge that TAF was a safer alternative to TDF ***and*** that it delayed commercialization of TAF "solely to maximize Gilead's profits."

Gilead first argued that there is a categorical exception for FDA-approved drugs accompanied by adequate warnings that are not shown to be defective.[19] Alternatively, Gilead proposed a narrower exception that plaintiffs could "assert a claim for negligence without proof of a defect, but only as to decisions the . . . manufacturer made after obtaining the results of Phase III clinical trials of the alternative"

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[13] *Id.* at 922.

[14] *Id.* at 948–50 (emphasis added).

[15] *Id.* at 950.

[16] *Id.* at 922.

[17] *Id.* at 927.

[18] *Id.* at 933.

[19] *Id.* at 917.

medication.[20] In other words, the narrower exception proposed that "the amount of knowledge necessary to trigger the imposition of a duty of care cannot exist before the manufacturer has the results of Phase III trials of the alternative drug."[21]

The court first considered the proposed categorical exception under *Rowland*. The first three *Rowland* factors, or the foreseeability factors, are: foreseeability of injury, degree of certainty that plaintiffs suffered injury, and closeness of the connection between the defendant's conduct and the injury.[22] The court found these factors weighed against the exception. According to the court, it was foreseeable that Gilead's delay in commercializing TAF would "cause some users to suffer injury they could have avoided had the new drug been available."[23] While the court recognized that there may be differences in the relative safety and efficacy between two drugs that could impact the "extent of harm"—and thus foreseeability—it found that this did not justify an exception where (as it assumed here) the new drug "is ***at least equally*** effective ***and*** poses a lower risk of side effects."[24] Likewise, the court acknowledged that "there is often considerable uncertainty associated with" FDA approval and cautioned against "hindsight bias."[25] But it was "not persuaded that the need for FDA approval necessarily . . . sever[ed] what would otherwise be a close connection" because in its view, there necessarily comes a point in time when a drug manufacturer can assess the likelihood of FDA approval.[26] Here, it believed approval was "far less uncertain than might otherwise be" for TAF because it had accepted the premise that Gilead ***knew*** TAF "to be as effective as, and safer than," TDF based on its Phase I/II testing.[27]

The remaining four *Rowland* factors, or the public policy factors, that the court evaluated were: moral blame, policy of preventing future harm, the burden to the defendant and consequences to the community, and availability and cost of insurance.[28] Among other things, the court stated that the most important factor is the prevention of foreseeable harm, which weighed against the exception because finding a "duty would prevent manufacturers from delaying the development of safer treatments."[29] The court accepted plaintiffs' allegations that Gilead acted to gain financial benefit. While it did not find that this "***precise*** conduct" was a factual prerequisite, it did confirm that there must be some showing of negligence: "our task is to evaluate the degree of moral blame that attaches to *negligence* in a drug manufacturer's decisions about commercializing a safer drug, not to potential non-negligent reasons for its actions."[30]

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[20] *Id.* Phase III trials "'consist of wide-scale studies on patients with the disease for which the drug is intended and evaluate the overall risks and benefits of the drug'" and "are the final stage in the process required to obtain approval of a new drug." *Id.* at 945 (citation omitted).

[21] *Id.* at 946.

[22] *Id.* at 938.

[23] *Id.*

[24] *Id.* (emphases added).

[25] *Id.* at 940.

[26] *Id.*

[27] *Id.*

[28] *Id.* at 941.

[29] *Id.* at 945.

[30] *Id.* at 942 (emphasis in original).

Second, the court left open whether Gilead's proposed narrower exception—that a duty attaches only after a Phase III trial—for another day. Gilead for its part argued that a manufacturer would not be able to foresee with sufficient confidence that a new drug would have an improved safety and efficacy profile until the conclusion of Phase III trials—wide-scale studies in patients which form the basis of FDA approval.[31] Plaintiffs argued that Phase I and II trials can provide significant information and the level of knowledge will vary based on the facts at hand.[32] The court, explaining that the record on these questions had not been developed in the trial court and thus it did "not know, for example, how often or under what circumstances a drug's apparent promise after Phase II is undermined by unexpected results in Phase III," held that Gilead had not established that such an exception was appropriate.[33] But the court nonetheless recognized the "potential availability" of such an exception and allowed Gilead to further develop the record before seeking the narrower exception from either the trial court or on appeal.[34]

THE IMPACT

Gilead will undoubtedly be a cause for concern for many pharmaceutical manufacturers worried about increased product liability exposure. We think, however, that plaintiffs will have difficulty expanding *Gilead* beyond the particular facts at issue here.

First, the *Gilead* holding is premised on an "actual knowledge" requirement, meaning that, to impose a duty, a manufacturer must actually possess knowledge that an alternative medication is safer than, and equally effective as, an existing medication.[35] Gilead did not contest that it knew TAF was safer and as effective as TDF for purposes of its petition, and thus the court assumed that actual knowledge had been established.[36] The court was clear, however, that its conclusion did not prevent Gilead from further developing the factual record in the trial court—or, if necessary, on appeal—to contest the basic allegations underpinning its analysis.

Admittedly, the court did not foreclose the possibility that these or other plaintiffs could show a duty that is premised on the less-stringent constructive knowledge standard (i.e., what the manufacturer ***should have*** known), which could expand potentially liability.[37] But the court also cautioned that liability without actual knowledge would be difficult because "actual knowledge appears to be necessary to the motivation plaintiffs attribute to Gilead's decision."[38] The court also explained that a different *Rowland* analysis would be required because "among other things, a constructive knowledge standard would be more susceptible to hindsight bias by the

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[31] *Id.* at 945–46.

[32] *Id.* at 946.

[33] *Id.* at 946–47.

[34] *Id.* at 948.

[35] *Id.* at 921–22, 937.

[36] *Id.* at 921–22.

[37] *Id.* at 922 n.5 ("we take no position on whether plaintiffs should be permitted to include a constructive knowledge theory on remand").

[38] *Id.*

jury and therefore present more challenging policy issues."[39] And assuming actual knowledge is required—which we think it will—plaintiffs could face substantial hurdles in surviving even the pleading stage because California is a fact-pleading state that would require specific factual allegations demonstrating actual knowledge.

Second, the court left the door open for Gilead to develop the factual record on its clinical trial program and re-argue for the narrower exception tied to Phase III clinical trials. Because the court put the burden on Gilead to prove the exception applies, it is unclear whether the court would endorse a categorical exception for ***all*** manufacturers based on the record Gilead develops—e.g., "any meaningful generalizations about what can reasonably be known after Phase II trials as compared to Phase III trials, and what those generalizations would be"[40]—or would instead require ***each*** manufacturer to prove the exception on a case-by-case basis, potentially necessitating costly discovery before resolution. Either way, the argument for the exception to apply has legs to stand on. Unlike Phase II clinical trials that merely test whether a new medication works for a certain type of disease, "Phase III clinical trials compare the safety and effectiveness of the new [medication] against the current standard [medication]."[41] Assuming courts reject a constructive knowledge standard, it may be hard for plaintiffs to show a manufacturer actually knew the new medication is safer than the current medication without first completing Phase III trials specifically designed to make such a comparison.

Viewing the decision with a glass-half-full outlook, *Gilead* as it currently stands applies only to the seemingly rare situation where a manufacturer developed both the existing and alternative medications, actually knew the alternative is safer than, and provides the same benefits as, the existing medication, and acted negligently in delaying the commercialization of the alternative medication. Indeed, the court went out of its way to say that it was creating a narrow duty that did not apply to "improved" products or require manufacturers to take steps to perfect their products. The way the court put it likely holds some truth: "if this situation were common, the claim likely would have arisen long ago."[42]

We will have to wait to see how the case plays out, as the California Supreme Court, in a rare move, granted Gilead's petition for review on May 1, 2024. Briefing before the Court will likely close by October 2024, but the Court might not issue a decision until late 2025. In the meantime, in-house counsel should keep abreast of the results of any clinical testing for "improved" medications in the pipeline and any decisions regarding their commercialization.

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[39] *Id.* at 937.

[40] *Id.* at 946.

[41] *Types and Phases of Clinical Trials*, AM. CANCER SOC'Y (Aug. 18, 2020), https://www.cancer.org/cancer/managing-cancer/making-treatment-decisions/clinical-trials/what-you-need-to-know/phases-of-clinical-trials.html.

[42] *Gilead*, 98 Cal. App. 5th at 944.