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Litigators of the (Past) Week: California Justices Reject Liability for a Drugmaker's Path Not Taken

By Ross Todd

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Our Litigators of the (Past) Week are **E. Joshua Rosenkranz** and **Andrew Silverman** of **Orrick, Herrington & Sutcliffe**. They persuaded the California Supreme Court to reject claims that their biopharma client Gilead Sciences should have developed and marketed a purportedly safer HIV drug sooner, a ruling that could eliminate nearly 23,000 cases.

The court's 6-1 decision last week held that Gilead could not be sued for injuries tied to its concededly nondefective TDF drugs based on allegations that it should have pushed an allegedly safer alternative, TAF, to market sooner—reversing a First District Court of Appeal decision that would have allowed the claims to move forward. Justice Joshua Groban, writing for the majority, framed the proposed duty as a threat to courts' ability to police drug-development decisions made amid scientific uncertainty, warning that imposing liability in those circumstances "would also risk distorting research priorities and chilling pharmaceutical innovation in ways that may ultimately undermine, rather than advance, public health and safety."

Justice Kelli Evans, the lone dissenter, said the majority was giving pharmaceutical companies "sweeping immunity" from negligence claims tied to allegedly unreasonable delays in commercializing safer drugs. But the majority emphasized that its ruling did not shield drugmakers from traditional product-defect, warning, fraud or statutory claims. Rather, it declined to recognize what amounted to a new duty to bring a different drug to market sooner—a theory that drew amicus attention from well beyond the pharmaceutical industry.

Litigation Daily: Who was your client and what was at stake?

Josh Rosenkranz: Our client was Gilead Sciences, a biopharmaceutical company that pioneered some extraordinary breakthrough medicines. One of its earliest breakthroughs was a medicine that cured hepatitis C. The one at issue in this case, TDF, transformed HIV/AIDS from a death sentence to a treatable illness, allowing people to live full and complete lives.

What was at stake was nothing less than the innovator's model of building on and improving existing medicines as well as developing breakthrough new treatments. Gilead's TDF had saved millions of lives. Plaintiffs conceded those medicines were not defective and were accompanied by adequate warnings about potential side-effects—which would ordinarily preclude any liability. But plaintiffs claimed Gilead nevertheless was liable because it took too long to develop an alternative medicine (TAF) that diminished the side-effects for some patients. It was a "duty to innovate." And the lower courts condoned it.

The California Supreme Court captured the stakes when it explained that this novel duty "threaten[ed] to skew innovation priorities in a manner that does not advance—and may ultimately undermine—public health and safety." As I said to the California Supreme Court, this would be the only duty in the history of tort law that arises because the manufacturer developed a different product that might be safer for some people. That would have discouraged manufacturers from improving existing products. And it would have forced manufacturers to divert resources from potentially game-changing new treatments to efforts aimed at mitigating side effects of existing medicines.

Andrew Silverman: As we'll discuss, that is why patient advocates, healthcare organizations, economists and academics joined a chorus of amici raising alarms about the public health consequences of this new duty. And the ramifications extended far beyond the context of prescription medicines, which is why just about every sector joined the pharmaceutical industry as amici: medical devices, the auto industry, technology companies, consumer product developers and manufacturers of all types.

The stakes for Gilead itself were also enormous. As is often the case when a manufacturer is sued over a popular medicine, this case involved tens of thousands of plaintiffs (here, about 23,000), each seeking untold damages. And there were considerable reputational issues, because plaintiffs had spun a false tale, refuted by the record evidence, that Gilead knew the alternative medicine was safer, yet sat on it for a decade to increase profits on existing medicines.

How did this matter come to you and the firm?

Rosenkranz: Gilead and Orrick have long been partners on several of Gilead's most important litigations, and Andrew and I have both worked closely with Gilead for years. Gilead brought us in to help develop legal strategy, draft important briefs, preserve key issues for appeal and handle appeals as they arose. This case is our sweet spot: issues at the intersection of law and public policy.

Who all was on your team and how did you divide the work?

Silverman: Our initial role was to lead the summary judgment briefing aimed at issues common to all 23,000 plaintiffs. Because of the law-intensive nature of that motion, the team was led by members of Orrick's Supreme Court & appellate group: myself, **Naomi Scotten**, **Cesar Lopez-Morales** and **Anne Savin**.

When we petitioned the Court of Appeal for an immediate emergency appeal, Josh joined the team as lead appellate counsel. We also added attorneys **Emily Villano** and **Lisa Bixby** in the Court of Appeal and Supreme Court.

Your team helped shape the summary judgment motion in this case with an eye toward

a possible appeal, then sought an emergency writ after losing in the trial court. What did you see in the plaintiffs' theory that made you willing to pursue such a strategy rather than going the traditional route of testing the issues through bellwether trials?

Silverman: This was a high-risk, high-reward strategy, and we have to hand it to Gilead for having the courage to pursue it.

Two key ingredients drove the decision. First was how radical the plaintiffs' theory was. Every treatise will tell you that you cannot sue a manufacturer for injury from its product without proving some form of a defect—in design, manufacturing or warnings. No court anywhere in the country had rejected this defect requirement. They all agreed that it struck the right balance. Second was how clearly we saw the disastrous consequences of the plaintiffs' novel new duty.

But the strategy presented two risks. First was a complication of the procedural posture. As I mentioned, plaintiffs had spun false narrative that Gilead knew back in 2004 that TAF was safer and equally effective and delayed TAF development just to make more profit. Since this was summary judgment and we needed to tee up a pure legal issue, we had to argue that there was no duty to develop TAF even if that was true. Second, the one-sided summary judgment record comprised of documents plaintiffs had cherrypicked out of context, made it harder to tell the full narrative of why Gilead made the development decisions it made. In the end, we concluded that the truth was evident even on the face of that sparse record—that Gilead could not know whether TAF was safer and it made not just reasonable, but laudable, development decisions that saved millions more lives.

Seeking review carried the risk that the court could establish this theory as binding California law. How did you and Gilead weigh the risk of creating unfavorable statewide precedent against the possibility of resolving the entire docket?

Rosenkranz: Oh, right, that was a third risk. The California Supreme Court is proud of its long history of recognizing new tort duties.

But Gilead and our team concluded that it was a risk worth taking. We felt strongly that law, logic and public policy were on our side. This new duty was poised to wreak havoc across many sectors. And Gilead felt a solemn obligation to industry and to patients to help the courts get the law right. Prevailing on our view of the law would also have the effect of resolving the entire docket of 23,000 cases—before a single case ever went to trial—and that was obviously an attractive proposition. But for Gilead, the underlying principle was much bigger than that.

Josh, your opening during oral argument before the California Supreme Court identified four potential social costs to allowing these sorts of claims to proceed, including deterring research into backup medicines and exposing manufacturers to liability for every "path not taken." How did you develop that framework, and, going in, which of those consequences did you think was most likely to move the court?

Rosenkranz: That opening was an important part of our strategy. The conventional approach in an appeal is to start with the law and sneak in some policy. But precisely because the California Supreme Court is comfortable breaking with the past and forging its own path in tort law based on its own evolving policy assessment, we decided to defy that conventional wisdom

and start with policy. The path to persuading the court depended on convincing the justices that this duty was against the public interest.

The precise articulation and order of those four social costs was the product of listening to many sources of input. We had input from so many stakeholders. And our amici included representatives of multiple industries, healthcare experts and patient advocates. From there, we focused on the consequences that we thought would most resonate with the court: It would yield bad decisions that undermined public health.

Whenever you have multiple points, you never know whether you will get them all out. So, I led with the ones that seemed most persuasive from a public health perspective and that could be illustrated by emphasizing the most salient facts of our case.

Justice Kelli Evans asked whether there might be a cause of action if a manufacturer delayed a drug after Phase III trials with full knowledge of the harm and solely to increase profits. Justice Joshua Groban pressed another hypothetical involving internal documents showing that a company knew an alternative was safer but considered it too expensive to develop. Did those exchanges make you concerned that the court was searching for a way to preserve some version of the plaintiffs' theory?

Rosenkranz: Yes, that was a concern. But this is what I love about arguing appeals. We put so much effort into preparing that there is never a question that we haven't workshopped. When the justices posed these and other hypotheticals, I knew exactly where I wanted to go with my answers. For each, I wanted to convey that the combination of existing law and financial incentives makes each edge case either highly unlikely to arise or redressable under current law. There was no reason to invite the disastrous consequences of this new duty to solve a problem that did not exist.

Your team marshaled support from more than 70 amici, including companies outside of life sciences. How did that coalition affect the way you were able to present the case?

Silverman: As Josh noted, many of the arguments in the Supreme Court turned on the policy consequences of the plaintiffs' proposed duty. Though we were fully able to brief those issues, third parties with no pecuniary interest in the outcome of the case were able to do so even more powerfully. Having the support of so many amici—in particular, a community of patient advocates and healthcare professionals—allowed us to lean into the policy arguments that ultimately carried the day.

The majority opinion places considerable weight on the fact that the TAF study lasted only 14 days and involved 30 subjects, 20 of whom received TAF. How much did the scientific record play into how the court weighed questions of comparative safety and negligence?

Silverman: The issue before the court was a purely legal issue regarding the existence and scope of a duty premised on the false narrative that Gilead actually knew that TAF was safer for some patients in 2004. We knew a Supreme Court wasn't going to resolve the question of knowledge, but we thought that the weakness of the plaintiffs' evidence would powerfully illustrate the dangers of this proposed duty: If a single two-week, 30-person study was enough to force a manufacturer to invest years of time and resources to bring an alternative product all the way to market, then

the duty would be nearly boundless. And if a plaintiff could get to the jury on such minimal evidence, the costs of such a duty in terms of litigation expenses and verdicts premised on hindsight bias would be astronomical.Beyond that, though, we just couldn't let the charges of Gilead knowingly withholding a safer medicine go unrefuted, especially when those accusations were demonstrably false. Even if it did not factor into the opinion, we felt an obligation to defend the integrity of Gilead and its scientists.

What can others take from the way that you, your team and Gilead litigated this case?

Rosenkranz: Two lessons. First, sometimes—I'd like to think almost always—standing up for principle pays dividends. It took a lot of guts for Gilead to defy some of the conventional wisdom to fight against a duty that would so severely hamper innovation. But the Gilead legal team never wavered in pursuing what they believed to be the right result against all obstacles.

Second, for me, this case stands as another stark example of the importance of preparing for a possible appeal while still in the trial court and making sure that expert legal strategists are thinking through and briefing these issues with an eye toward an eventual appeal. When I first got into the case, I was grateful for how brilliantly Andrew and his team had teed the case up for appeal.

What will you remember most about this matter?

Rosenkranz: For me, there were two moments that bookended my involvement in the case. First, when I dug below the surface, I remember how angry I was in realizing that the plaintiffs' narrative was demonstrably false. These were brilliant and devoted scientists who changed the world by helping to stem the tide in the war against HIV/AIDS. They made the right decisions for the overall good. And even that small study showed TDF and TAF to have a "similar safety profile." Then, on the back end, standing before the Supreme Court, I remember the satisfaction of hearing multiple justices echoing our key themes and narrative points in ways that displayed their firm grasp of the truth.

Silverman: The many amici who conveyed to the California Supreme Court just how important this issue was to them. That included not just the many companies who took the rare step of signing briefs in their own names, but also patient advocates who were targeted and criticized for daring to ever side with a pharmaceutical company. It made a huge difference.