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IN THE SUPREME COURT OF CALIFORNIA

Gilead Tenofovir Cases

After a Decision by the Court of Appeal
First Appellate District, Division Four Case No. A165558

Application for Leave to File *Amici Curiae* Brief and Proposed Brief of *Amici Curiae* Product Manufacturers and Affiliates in Support of Petitioner Gilead Sciences, Inc.

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Amici Archer Aviation, Inc.; Bayer U.S. LLC; Becton, Dickinson and Company; Biogen Inc.; Bristol Myers Squibb Company; Corteva Agriscience LLC; Cytokinetics, Incorporated; The Dow Chemical Company; DuPont de Nemours, Inc.; Eli Lilly and Company; GE Healthcare Technologies, Inc.; Genentech Inc.; General Motors LLC; Glaukos Corporation; GSK LLC; Hamilton Beach Brands, Inc.; Hyundai Motor America; Incyte Corporation; Johnson & Johnson, Inc.; Kenvue Inc.; Kia America, Inc.; Organon & Co.; Medtronic, Inc.; Merck & Co, Inc.; Pfizer, Inc.; Regeneron Pharmaceuticals, Inc.; Roche Molecular Systems, Inc.; Sanofi US; Sonoma Biotherapeutics, Inc.; STORM Therapeutics Ltd.; Takeda Pharmaceuticals U.S.A., Inc.; Toyota Motor North America, Inc.; Vertex Pharmaceuticals Inc.; Volkswagen Group of America, Inc.; and Zimmer Biomet Holdings, Inc. request permission under California Rule of Court 8.520(f) to file this

amici curiae brief in support of Petitioner Gilead Sciences, Inc.[1]

The brief will assist the Court in deciding this matter in two ways. First, *amici* are product manufacturers or their distributor affiliates: they have unique, first-hand insight into the legal and practical issues presented in this case. A key part of *amici*'s businesses is researching, developing, and bringing new products to market. Virtually every day, *amici* and their affiliated companies must make complex, strategic decisions about how to allocate their finite resources across their research-and-development pipelines and product portfolios. *Amici* are uniquely positioned to explain how the Court's decision will impact those product-development decisions.

Second, *amici* draw on their unique knowledge and experience to explain how important policy considerations weigh against adopting the duty and liability standards that Plaintiffs propose. Plaintiffs seek to impose a sweeping, unprecedented duty that would require manufacturers to rush a product to market as soon as they supposedly "know" that this product is marginally safer for at least some consumers. As *amici* explain, this drastic expansion of tort liability will hinder product innovation—which will ultimately harm consumers by impeding new product development.

No party or counsel for a party in this pending appeal authored any part of the *amici curiae* brief or made any monetary

[1] Corteva Agriscience LLC is represented by Cohen Williams LLP. All other *amici* are represented by O'Melveny & Myers LLP.

contribution intended to fund the brief's preparation or submission. No person or entity other than *amici* made a monetary contribution intended to fund the preparation and submission of the brief.

AMICI CURIAE

Amici and their affiliated companies are global leaders in researching, developing, manufacturing, and commercializing products across a range of consumer, automotive, pharmaceutical, biotechnology, and medical-device markets. *Amici* and their affiliated companies have a long history of researching, developing, and bringing innovative products to market. Together, *amici* and their affiliated companies employ many thousands of individuals and spend tens of billions of dollars annually on research and development for new and innovative treatments, technologies, goods, and services.

INTEREST OF *AMICI CURIAE*

Amici have a strong interest in the Court's decision in this case. When researching, developing, manufacturing, and distributing products, *amici* and their affiliated companies must be mindful of the need to comply with legal requirements, including tort duties. Companies like *amici* rely on clarity, stability, and predictability in these legal requirements to make business decisions about how to allocate finite resources—whether by making their existing products safer, more efficacious, or less costly, or investing in research and development for new products to address unmet needs. The Court's decision is critical to *amici* because Plaintiffs' proposed

duty threatens to inject significant and intolerable risk and instability into *amici*'s and other companies' efforts to fulfill their legal duties when researching, developing, and bringing their products to market.

CONCLUSION

Amici request that the Court accept the accompanying brief for filing in this case.

Dated: November 4, 2024 Respectfully submitted,

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AMICI CURIAE **BRIEF**[2]

INTRODUCTION

Product-development decisions are complex. In determining which products to research, develop, and bring to market, manufacturers must decide how to allocate finite resources across their research-and-development pipelines and product portfolios. Product manufacturers must carefully balance competing interests, including those of consumers, shareholders, or regulators, as well as economic, legal, and ethical considerations. And any product-development decision is at best predictive: manufacturers operate under significant conditions of uncertainty, and they can never know for sure that a given development program will succeed.

Until now, product manufacturers' decisions about how to manage their research-and-development pipelines and product portfolios have not been subject to tort liability. But Plaintiffs say they should be. Plaintiffs claim that product manufacturers have a duty to commercialize alternatives to their non-defective, existing products as quickly as possible, just as soon as they purportedly know that the alternative product might be safer for at least some consumers. (Plaintiffs' Answering Brief ("AB") at 1, 8.) Under Plaintiffs' proposed duty, manufacturers would be potentially liable in tort any time they discover a supposedly safer, equally efficacious alternative to an existing product and

[2] Unless stated otherwise, all emphasis is added to, and all citations and internal quotation marks are omitted from, the quoted material.

delay bringing that alternative product to market—and *even if the existing product is not defective*.

Such a rule would have sweeping consequences. As Petitioner Gilead Sciences, Inc. has explained in its briefs, Plaintiffs' proposed duty threatens unprecedented liability likely to disincentivize product manufacturers from innovating new and better products. (Petitioner's Opening Brief ("OB") at 34-37, 50-54; Petitioner's Reply Brief ("RB") at 35-36.) If manufacturers were liable for failing to market alternatives to their non-defective existing products, manufacturers would be incentivized to avoid research that might lead them to acquire knowledge about potentially safer alternatives. (OB at 50-53.) And if manufacturers did develop that knowledge, the risk of tort liability would push them to then prioritize commercializing that alternative over developing new products that might be even safer or more beneficial for more consumers. (*Id.*) As Petitioner further explains, the breadth of Plaintiffs' proposed duty creates an unworkable legal standard that would make the threat of liability—and thus the consequences of manufacturers' product-development decisions—unpredictable, leading manufacturers to overcorrect. (*Id.* at 45-47.)

Plaintiffs dispute these consequences. They claim that, despite the liability indisputably threatened by their proposed duty, product manufacturers will still be sufficiently incentivized to innovate in order to "win[] market share," "avoid[] reputational damage," and "maximize profits." (AB 44-46.) Plaintiffs further argue that their proposed duty provides sufficiently clear

standards for courts and juries to evaluate companies' product-development decisions, as liability would turn on the "reasonableness" of a manufacturers' decision—a concept that courts and juries apply in other tort cases. (AB 31-32.)

Both of these arguments are deeply flawed, as *amici* here write separately to explain. Plaintiffs' proposed duty will transform manufacturers' research-and-development pipelines and product portfolios into a minefield of tort liability that will distort product-development decision-making in three key ways. First, Plaintiffs' proposed duty will disincentivize manufacturers from exploring innovative improvements to their existing products. Because Plaintiffs' proposed duty seeks to punish manufacturers that know of potential improvements to existing products and delay or forgo commercializing those improvements, manufacturers will be incentivized to avoid the kind of research and development that might identify such improvements—and potentially lead to even more ground-breaking solutions. Second, the threat of liability will push manufacturers to prioritize commercialization of new products that offer incremental improvements to existing products over the development of innovative new products that might fill different or greater unmet needs. Lastly, the proposed duty and attendant litigation over alleged breaches of that duty will reduce the resources available to manufacturers to invest in innovation of any kind. Increased liability exposure will increase the cost of every research-and-development project, limiting manufacturers' ability to devote resources to innovative products.

Plaintiffs' proposed duty is also unworkable as a practical matter. Plaintiffs would invite courts and juries "into the boardroom," asking them to second-guess companies' complex and strategic decisions on how to manage their product-development pipelines and product portfolios. Scrutinizing this kind of corporate decision-making is not only outside the competency of courts and juries, but is inherently tainted by significant hindsight and context bias. Courts and juries would be asked to judge a manufacturer's product-development decisions with the benefit of 20/20 hindsight, using vague and nebulous standards about what a hypothetical, supposedly "reasonable" product manufacturer would have done had it been sitting in the shoes of the particular manufacturer-defendant. And because this evaluation would necessarily occur in the litigation context, courts and juries would have before them as plaintiffs only the handful of individuals allegedly harmed by that company's product-development decision—not the many consumers who benefited from that decision—leading to skewed and unjust results.

ARGUMENT

I. PLAINTIFFS' PROPOSED DUTY WILL HARM INNOVATION

Amici, their affiliated companies, and countless product manufacturers like them constantly make decisions about how to manage their research-and-development pipelines and product portfolios, including which projects to pursue and at what pace. Those decisions are far from simple. They involve many stakeholders—from *internal* stakeholders like directors,

employees, and shareholders, to *external* stakeholders like creditors, investors, customers, and the community that the company serves. They also involve a multitude of different factors—from *economic* considerations like the company's current and projected future financial condition and the broader macroeconomic environment that the company is operating in; to *legal* considerations like the regulatory landscape that the company operates in; to *ethical* considerations like a company's social responsibility to the public. This complexity is compounded by the reality that, when companies decide whether, how, and when to research, develop, and bring a new product to market, they do so with finite resources and under conditions of significant uncertainty.

The consequence of this complexity is that product-development decisions involve tradeoffs. Companies cannot invest in an unlimited number of research-and-development opportunities and must make choices about whether to focus on improving their existing products or in developing new products, and how to allocate finite resources among different opportunities. Such considerations influence not only which projects to proceed with, but also their timelines. Because product-development decisions are so complex and require companies to balance the competing interests of multiple constituencies, this kind of corporate decision-making demands sophistication, experience, expertise, and—most of all—judgment. It is no surprise that companies frequently rely on outside consulting firms, economists, financial-services

companies, and regulatory experts to help them determine how to manage their research-and-development pipelines and product portfolios.

Plaintiffs' proposed duty ignores this complexity. As Plaintiffs would have it, manufacturers must put all these competing considerations aside when making their product-development decisions. Instead, Plaintiffs say, manufacturers should have an affirmative obligation to research, develop, and bring to market incremental alternatives to their existing, non-defective products so long as the company supposedly "knows" that such an alternative might be safer for at least some consumers—regardless of the costs of doing so, regardless of trade-offs in efficacy, and regardless of how this may impact the company's research-and-development pipelines and product portfolios more broadly. And Plaintiffs suggest that, even if the manufacturer successfully commercializes such an alternative to its existing, non-defective product, the manufacturer should still face litigation and potential tort liability on the theory that it should have brought the alternative to market even sooner.

Needless to say, Plaintiffs' proposed duty would have substantial consequences for companies' existing product-development practices. And the resulting changes to those practices would stymie the development of new, innovative products. The end-result would be harm to consumers, who will have access to fewer cutting-edge, safe, and efficacious products. As *amici* next explain, Plaintiffs' proposed duty would harm innovation in three distinct ways: it will disincentivize

innovation in improved alternatives to existing products; it will distort companies' incentives to engage in the development of innovative new products addressing other needs; and it will reduce the resources available for innovation of any kind.

1. *Disincentivizes innovation.* First, Plaintiffs' proposed duty will discourage the development of innovative alternative products, as it purports to transform a company's efforts to innovate into a basis for tort liability.

Under Plaintiffs' theory, manufacturers could be subject to tort liability if they discover a potentially safer or more efficacious alternative to a non-defective existing product and either decide not to bring that alternative to market or fail to rush that alternative to market. This threat of liability will pressure companies to terminate research-and-development programs early to avoid acquiring knowledge that would obligate them to tie up their limited resources in commercializing potential alternatives to their existing products. As one legal commentator summed up the problem, Plaintiffs' duty "may force an innovator into a Catch-22 situation"—either "face[] liability for introducing a new product or innovation prematurely," or decline to "conduct[] further research into product improvements" altogether to avoid that potential liability.[3]

These concerns are real, not academic. Take, for example, pharmaceutical manufacturers like certain of the *amici*.

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[3] Gary Myers, Law 360, *Gilead Ruling Signals That Innovating Can Lead To Liability* (Feb. 6, 2024), https://www.law360.com/articles/1793143/gilead-ruling-signals-that-innovating-can-lead-to-liability [as of Nov. 4, 2024].

Pharmaceutical manufacturers must exercise careful judgment over how to allocate their finite resources. The process of researching, developing, and bringing new treatments and devices to market is long, costly, and risky—only a miniscule fraction of therapies under research-and-development ever obtain FDA approval or clearance.[4] Also, medical and scientific evidence is often indeterminate. Manufacturers rarely know with any degree of certainty whether a product in their research-and-development pipelines will prove to be safe and effective, much less commercially viable. This is true of both treatments and devices that incrementally improve on a company's existing products, as well as wholly new therapies.

Based on the imperfect information gained during the research-and-development process, manufacturers must decide which of the products in their pipeline they want to pursue further—including how much to invest in developing those products, and on what timeline. That uncertainty is compounded by the need for "complicated scientific and regulatory risk-adjustments (to account for the probability of FDA approval)," requiring manufacturers to "peer into an unknowable future" as

[4] See PhRMA, *Clinical Trials—So Necessary but More Complex Than Ever* (Mar. 3, 2011) [stating that only one out of every 5,000 to 10,000 pharmaceutical compounds under development obtains FDA approval], https://phrma.org/blog/clinical-trials-so-necessary-but-more-complex-than-ever [as of Nov. 4, 2024].

they make consequential choices about which products to develop.[5]

Moreover, because a company's resources are finite, a manufacturer's decision to prioritize the research and development of one product—such as investing in a pathbreaking new cancer treatment—will require trade-offs in the form of deprioritizing other research and development, such as investing in improved treatments with fewer adverse effects for common illnesses like arthritis. As the former chief counsel of the Food and Drug Administration recently explained: "[t]rade-offs are part of doing business," and "deciding which drug programs to progress involves delicate judgments about unmet patient needs, what prescribers believe they need, the likelihood and timing of potential FDA approval, the potential profitability of the program, the capacity and capability of the R&D and the rest of the organization, and a myriad of other factors."[6]

Plaintiffs would weaponize the complexity and uncertainty of the research-and-development process by turning manufacturers' judgments about the best path forward into a potential basis for tort liability. But injecting significant additional risk into the development of products that may offer improvements over existing products will disincentivize

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[5] Dan Troy, STAT: Reporting from the frontiers of health and medicine, *A California court is setting a dangerous precedent over drug development (or lack thereof) liability* (Feb. 13, 2024), https://www.statnews.com/2024/02/13/tdf-taf-gilead-lawsuit-ruling-hiv/ [as of Nov. 4, 2024].

[6] *Ibid.*

manufacturers from investing in those improvements in the first place. If, for example, pharmaceutical manufacturers face potential liability for not prioritizing treatments that might prove to have a better risk/benefit profile than treatments they previously brought to market, those manufacturers may forgo researching, developing, and seeking approval of improved treatments altogether. All the more so if pre-clinical studies (i.e., with animals and plasma) and early-stage clinical studies (i.e., with people) are later used against manufacturers as evidence that they supposedly "knew" the alternative treatments they opted not to pursue were more efficacious or safer in some respect—as Plaintiffs have tried to do here. (See AB 50-51 [relying on pre-clinical studies and a single early-stage clinical study to argue that Gilead "knew" TAF was safer than TDF in 2002].)

Indeed, Plaintiffs' theory—which seeks to impose liability on life-sciences manufacturers based on information obtained before the third phase of clinical trials (or "Phase III")—would sharply disincentivize innovation. (OB 60-64.) As Petitioner has explained in its briefing, the entire point of multi-phase clinical trials is to gain a better understanding of the safety and efficacy of a product with increasingly larger patient populations *before* that product is ever put on the market for consumer use. But that knowledge is often not available until certain pivotal clinical trials have been completed. Between 70-75% of drug candidates that start Phase III fail. (*Id.* at 61.) And research has shown that 17% of therapeutics fail at Phase III for safety reasons, and

57% of them fail for efficacy.[7] Before deciding to proceed with pivotal trials, manufacturers carefully balance that likelihood of failure against many other factors—such as unmet patient needs, competing portfolio priorities, commercial opportunity, and the strength of the prior Phases' datasets—all without actually knowing whether a drug candidate will be viable. Threatening manufacturers with liability for failing to continue the development of a drug candidate before they could know that the candidate will be safe or efficacious is not only nonsensical, but will also dissuade them from developing products that could go to pivotal trials in the first place.

The problems with Plaintiffs' theory are not limited to manufacturers in the life sciences. *All* manufacturers must make predictive decisions about how to allocate their limited resources across their research-and-development pipelines and product portfolios. A carmaker, for example, can come to learn that a cutting-edge driver-assist technology could make its cars marginally safer, but decide not to implement that technology in its entry-level model because it would price certain consumers out of the market with only a minimal incremental safety benefit. Or a carmaker could decide not to implement that driver-assist technology because, although the technology could help avoid certain types of accidents, other technologies—such as blind spot

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[7] David B. Fogel, *Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: review* (2018) 11 Contemp. Clinical Trials Comms. 156, 164, https://pmc.ncbi.nlm.nih.gov/articles/PMC6092479/ [as of Nov. 4, 2024].

indicators or side airbags—could have a greater impact, help avoid other potential accidents, make the car safer in other respects, or make the car safer in the same respects but at less cost to the consumer.

Under current case law, a manufacturer's decision to prioritize the development of one safe version of a product over another safe version of a product does not give rise to tort liability. The central requirement under tort law remains that whatever product ultimately goes to market, the manufacturer must ensure that the product is not defective. This standard makes sense. Manufacturers can be held liable when "the risk of danger inherent in [their product] outweighs [its] benefits." (*Kim v. Toyota Motor Corp.* (2018) 6 Cal.5th 21, 30.) To that end, courts have spent decades creating clear, stable, and predictable standards that courts and fact-finders use to determine when and whether a manufacturer should be held liable for bringing a product to market.

Plaintiffs' proposed duty would upend that established structure and replace it with significant uncertainty. Faced with potentially massive and unpredictable tort exposure, companies will be discouraged from researching and developing better alternatives to their products, harming the very consumers that Plaintiffs claim to protect.

2. *Distorts product-development decisions.* Plaintiffs' proposed duty will harm innovation in a second way: when a product manufacturer *does* develop knowledge of a safer alternative to an existing product, it will be incentivized to

prioritize commercializing that alternative over new and truly innovative products addressing other needs, including needs not addressed by existing products.

As Petitioner has explained in its briefing, Plaintiffs' proposed duty threatens companies with liability for the period of time that hypothetical, alternative products are *not* on the market: according to Plaintiffs, once a company discovers that there is (or could be) an alternative to an existing, non-defective product that is safer for a class of consumers, the company now has a duty to bring that product expeditiously to market. (OB 33-34.) This threat of liability will push companies toward incremental improvements of their existing products over researching and developing entirely new products to address unmet needs.

Take again the example of a pharmaceutical manufacturer deciding whether to prioritize research and development of a potentially pathbreaking cancer treatment over incremental improvements to the side-effect profiles of existing arthritis treatments. If the threat of liability forces the company to invest in the latter, the company may delay, divert resources from, or altogether forgo the research and development of the pathbreaking cancer treatment—a treatment that may benefit an entirely different class of patients, including patients who currently have no effective treatments at all.

Or consider again the carmaker deciding which research-and-development projects to pursue to enhance car safety features. It is well-established that driver-assistance

technologies help avoid accidents: according to the National Highway Traffic Safety Administration ("NHTSA"), they save thousands of lives a year.[8] But if a carmaker now faces liability for failing to bring to market marginally improved driver-assistance technology that it may have been developing in its pipeline, it will be incentivized to focus its limited resources in commercializing only *that* technology—rather than investing in brand-new, innovative technologies that have the potential to make consumers' driving experience safer overall and to save even more lives.

3. *Reduces resources for innovation.* Lastly, Plaintiffs' proposed duty will harm innovation by reducing the resources that are available to invest in developing innovative products.

Most obviously, throwing open a company's entire research-and-development pipeline and product portfolio to potential tort liability threatens significant litigation exposure and increased litigation costs. Because of the risk of exposure, companies will likely need to involve lawyers at every stage of their product-development decisions, adding further expense and delay to the research-and-development process. Claims, even if meritless, could involve massive litigation costs. In this case alone, 24,000 plaintiffs brought claims against a single manufacturer. (AB 32.) The cost of litigating such a massive number of claims through the pleading, discovery, and summary-judgment stages—let

[8] NHTSA, *Driver Assistance Technologies*, https://www.nhtsa.gov/vehicle-safety/driver-assistance-technologies [as of Nov. 4, 2024].

alone through trials and appeals—could impose a crushing financial burden on product manufacturers. And beyond litigation costs, intensive discovery into product-development decisions and the employees who made them would pull further time, resources, and attention away from ongoing research and development projects.

Moreover, product-liability cases often lead to high verdicts. Over the last decade, product-liability suits resulted in hundreds of millions of dollars in damages awards per year, peaking at over $1 billion in 2017.[9] Studies have found that product-liability cases are especially prone to "nuclear verdicts"—i.e., verdicts of $10 million or more.[10] Indeed, from 2013 to 2022, product-liability cases accounted for one-third of verdicts that reached $100 million or more.[11] And even if a company ultimately prevails at trial, it will still face inflated settlement demands during the course of any litigation. In fact, settlement demands can present an even greater risk than high verdicts: in 2022 alone, product-liability class actions and mass-tort suits led to more than $50 billion in settlements.[12]

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[9] Lex Machina, *Product Liability Litigation Report* (2023) at 25.

[10] U.S. Chamber of Commerce Institute for Legal Reform, *Nuclear Verdicts: An Update on Trends, Causes, and Solutions* (May 2024), https://instituteforlegalreform.com/wp-content/uploads/2024/05/ILR-May-2024-Nuclear-Verdicts-Study.pdf [as of Nov. 4, 2024].

[11] *Ibid.*

[12] Danielle Braff, ABA Journal, *Billion-Dollar Business: the High-Risk, High-Reward World of Mass Torts* (2023) at 33.

In short, Plaintiffs' duty threatens to consume even more of a company's limited resources, diverting money, time, and attention that could otherwise be spent on research and development. This will diminish the resources that are available for innovation of any kind.

II. PLAINTIFFS' PROPOSED DUTY IS UNWORKABLE

Plaintiffs' proposed duty will not only distort a company's product-development decisions, but it will also subject those same decisions to second-guessing by courts and juries. As a practical matter, this kind of scrutiny is unworkable. There are two reasons why: (1) evaluating product-development decisions like the kind at issue here is outside the core competencies of courts and juries, and (2) this evaluation will itself be tainted by significant inherent bias.

1. *Institutional competence.* This Court has long recognized that courts and juries are ill-suited to evaluate certain kinds of complex and strategic corporate decision-making. Indeed, this principle is uncontroversial and well-established in other areas of California law.

Take, for example, the business-judgment rule that this Court and others have adopted in the context of securities and fiduciary-breach litigation. That rule creates a presumption that a company's business decisions "are based on sound business judgment." (*Berg & Berg Enters., LLC v. Boyle* (2009) 178 Cal.App.4th 1020, 1045.) The effect of the rule is to "insulate[] from court intervention those management decisions which are made by directors in good faith," "in the absence of a conflict of

interest," and in pursuit of "what the directors believe is the organization's best interest." (*Ibid.*)

The basis for the business-judgment rule is a public-policy determination about the respective competencies of businesses on the one hand, and courts and juries on the other. As the Court has explained, the rule "derive[s] from the realities of business"—namely, that companies "should be given wide latitude in their handling of corporate affairs," and that "the judicial process is an imperfect device for evaluating business decisions." (*Lamden v. La Jolla Shores Clubdominium Homeowners Assn.* (1999) 21 Cal.4th 249, 259.) As another court put it, "those to whom the management of a business organization has been entrusted"—"not the courts"—"are best able to judge whether a particular act or transaction is helpful to the conduct of the organization's affairs or expedient for the attainment of its purposes." (*Berg*, *supra*, 178 Cal.App.4th at 1045.) Given those public-policy concerns, courts should not "interfer[e]" in a company's "business decisions made by the directors in good faith and in the absence of a conflict of interest," and "substitute [their] judgment for that of the board." (*Ibid.*)

The same reasoning applies here. Plaintiffs want to task courts and juries with evaluating how a hypothetical, "reasonable" product manufacturer—sitting in the shoes of the particular corporate-defendant—supposedly would have managed its research-and-development pipeline and product portfolio. That is, Plaintiffs say that courts and juries should decide the "reasonableness" of a manufacturer's complex and strategic

business decisions about whether, how, and on what timelines to develop, research, and commercialize changes to existing products as well as any new products. Those are exactly the kind of business decisions that this Court has recognized should *not* be subject to second-guessing through the litigation process.

Plaintiffs' only response is to say that these concerns are "misplaced," because courts and juries are supposedly "already entrusted with making complex risk/utility determinations in product liability cases." (AB 31-32.) But Plaintiffs' theory of liability is not a typical product-liability theory. And Plaintiffs' theory does not ask courts or juries to make the kind of "risk/utility determinations" that are at issue in typical product-liability cases. In a typical product-liability case, the alleged defective product is assessed against measurable benchmarks—degree of risk, feasibility of alternatives, and utility of the existing design. In that typical situation, the "risk/utility determination" for courts and juries is straightforward: did the particular benefits of the particular product design "outweigh" the particular risks in the design? (*Kim*, *supra*, 6 Cal.5th at 30.)

Plaintiffs' theory here, by contrast, asks courts and juries to engage in guesswork about what a supposed "reasonable" manufacturer's hypothetical, alternative product-development decisions would have looked like and what the hypothetical, alternative results of those decisions would have been—for example, what studies the manufacturer should have performed to determine whether the alternative product was market-ready; what trade-offs the manufacturer should have made when

designing the alternative product; and what other product improvements, product lines, or new product-development projects the manufacturer should have deprioritized in order to invest in the alternative product. Courts and juries—who are already ill-suited to evaluate complex and strategic business decisions—are especially ill-equipped to engage in this kind of speculation.

2. *Bias.* Not only are courts and juries ill-suited to evaluate a manufacturer's complex product-development decisions, but the evaluation will itself be tainted by significant bias.

The most immediate risk is "hindsight bias." Hindsight bias is the "tendency for individuals to overestimate or exaggerate the predictability of events after they have occurred." (*Chavez v. City of Los Angeles* (2010) 47 Cal.4th 970, 986-87.) Both this Court and the United States Supreme Court have cautioned that, when crafting liability rules, courts must be mindful of the "distortion caused by hindsight bias." (*KSR Int'l Co. v. Teleflex Inc.* (2007) 550 U.S. 398, 421; *Chavez*, *supra*, 47 Cal.4th at 986-87 [instructing courts to "exercise caution to avoid 'hindsight bias'"].) The risk of hindsight bias is especially high in the product-liability context, where a common tactic by plaintiffs is to try to prove liability based on information revealed only *after* the company made the challenged decision. (See *T.H. v. Novartis Pharms. Corp.* (2017) 4 Cal.5th 145, 187 n.8 ["To avoid the distortion caused by hindsight bias, trial courts should be careful to protect the jury from needlessly being exposed to or

considering scientific studies connecting a drug to some harm where those studies postdate [the relevant conduct]."])

Plaintiffs' theory of liability here only makes these problems worse. A manufacturer's decisions about how to allocate its finite resources across its research-and-development pipeline and product portfolios are necessarily predictive—made with imperfect information, and under conditions of significant uncertainty. Yet Plaintiffs' proposed duty would require courts and juries to second-guess the "reasonableness" of a manufacturer's product-development decisions with 20/20 hindsight after the fact—indeed, sometimes *decades* after those decisions were made. As a practical reality, courts and juries will be unable to put themselves into a company's shoes to evaluate its product-development decisions at the time those decisions were made. The reality is that Plaintiffs' theory effectively invites courts and juries to impose liability against manufacturers simply because, looking back, they happen to disagree with the company's business decisions.

This case is a perfect example. As Petitioner explained in its briefing, Gilead sought to develop a pathbreaking HIV treatment. (OB 11.) After years of pre-clinical research and clinical trials, Gilead obtained FDA approval in 2001 for tenofovir disoproxil fumarate ("TDF"). (*Id.* at 11.) While TDF was in clinical trials, Gilead developed a backup candidate: tenofovir alafenamide ("TAF"). (*Id.* at 13.) But research indicated that TAF had "potential toxicity" and "safety profiles *similar* to that of [TDF]"—suggesting that Gilead should instead invest its

resources in pursuing new combination treatments and once-a-day, single-pill regimens using TDF. (*Id.* at 13-15.) Gilead then stopped TAF development in 2004. (*Id.* at 15.) After TDF's success, Gilead decided to resume TAF research in 2010, when the success of these TDF-based single-pill regimens led to a newly aging patient population and circumstances where TAF became attractive as a potentially lower-dose alternative. (*Id.* at 16.) Only after years of additional research—including large-scale head-to-head clinical trials—did it become apparent that TAF was a viable alternative. (*Id.* at 16-17.)

In hindsight, it may appear to a court or jury that Gilead should have developed TAF sooner. But when Gilead made the decision not to pursue TAF, it had no certainty about whether TAF would be a viable candidate, let alone a better one. In fact, the data at the time was to the contrary. (*Id.* at 13-15.) Had Gilead invested in TAF, it is entirely possible that it would have spread its resources too thin and been unable to develop the single-tablet treatment that made TDF-based medicines so effective—depriving consumers of a medicine that saved thousands of lives. Courts and juries will have difficulty imagining these alternative scenarios.

On top of this hindsight bias, Plaintiffs' theory also threatens "context bias." Context bias is the propensity to interpret facts based on the circumstances in which they are presented. The litigation context—and product-liability litigation in particular—presents an especially high risk of context bias. In product-liability cases, only the *plaintiffs* are before the court and

the jury. That is, the court and jury see only those individuals who were allegedly injured by a manufacturer's allegedly defective product. But what courts and juries do *not* see are the many individuals who have benefitted, and will benefit, from the manufacturer's product—potentially more so than they would have from the alleged alternative. As the United States Supreme Court explains, a jury sees "only the cost of a more dangerous [product], and is not concerned with its benefits," and "the [consumers] who reaped those benefits are not represented in court." (*Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312, 325.) This Court has expressed the same concern, explaining that "the question of the superiority of one [product] over another would have to be decided not in the abstract but in reference to the plaintiff," who presents only the alleged risks of a product rather than its benefits. (*Brown v. Super. Ct.* (1988) 44 Cal.3d 1049, 1061.)

Here too, Plaintiffs' theory of liability only makes these problems worse: even if a manufacturer acted perfectly reasonably—for example, by opting to invest its limited resources in researching and developing safe and effective products for unmet consumer needs that benefit more consumers than the incremental improvements to existing products that Plaintiffs say should be commercialized instead—courts and juries still will have before them only those individuals who were allegedly harmed by that manufacturer's choice. They will not have before them the numerous individuals who benefitted from the other

efficacious, beneficial, and safe products that resulted from that decision.

Take again the pharmaceutical manufacturer sued for its decision to delay commercializing improved arthritis treatments with fewer or different side-effects than its existing FDA-approved treatments in favor of developing an innovative new cancer treatment. The court and the jury would have before them only those patients who were allegedly harmed by the known potential adverse effects of that company's arthritis medications. But the court and the jury would not have before them the many cancer patients whose lives were saved by the alternative innovation that the company pursued.

The same is true for the carmaker that opts not to adopt driver-assist technology because it does not want to price its customers out of the market, and instead opts to implement back-up cameras or a collision alert system. While the court and jury may have before them drivers injured by certain lane changes, they would never see the many other drivers who were able to afford, purchase, and safely drive those non-defective cars without incident, or whose lives were saved by the alternative safety innovations they contained.

CONCLUSION

The Court should reverse.

Dated: November 4, 2024 Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 8.204 of the California Rules of Court, the foregoing is proportionally spaced and contains 5,197 words, according to the word processing program used to prepare it.

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PROOF OF SERVICE

I am over the age of 18 years and not a party to this action. I am employed in the County of Los Angeles, State of California. My business address is 400 South Hope Street, Suite 1900, Los Angeles, CA 90071.

On November 4, 2024, I served the following document(s) described as

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