IN THE SUPREME COURT OF CALIFORNIA

GILEAD TENOFOVIR CASES.

S283862

First Appellate District, Division Four
A165558

San Francisco City and County Superior Court
JCCP No. 5043

August 3, 2026

Justice Groban authored the opinion of the Court, in which Justices Corrigan, Liu, Kruger, and Desautels* concurred.

Chief Justice Guerrero filed a concurring opinion.

Justice Kruger filed a concurring opinion in which Justices Corrigan and Desautels* concurred.

Justice Evans filed a dissenting opinion.

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* Associate Justice of the Court of Appeal, First Appellate District, Division Two, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.

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Opinion of the Court by Groban, J.

This case requires us to determine whether a drug manufacturer may be liable in negligence for injuries allegedly caused by a drug used by plaintiffs that plaintiffs concede is not defective. Specifically, plaintiffs allege that defendant Gilead Sciences, Inc. (Gilead), is liable in negligence because it unreasonably delayed bringing to market another drug it had invented that was equally effective and less toxic than the nondefective drug that allegedly caused plaintiffs' injuries. Plaintiffs allege that they would have switched to the alternative drug and avoided injury had Gilead not unreasonably delayed bringing the alternative drug to market. The Court of Appeal held that liability may attach in these circumstances. (*Gilead Tenofovir Cases* (2024) 98 Cal.App.5th 911, 916–917.)

The Court of Appeal acknowledged our precedent suggesting that, when a plaintiff sues a manufacturer under a products liability theory for injuries caused by one of its products, the plaintiff generally must prove that the product was defective. (See *Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 929.) But the court nonetheless considered it an open question whether alleging a defect is always necessary, and concluded plaintiffs need not allege a defect here. (*Id.* at pp. 929–930.) The Court of Appeal reasoned that plaintiffs need not allege a defect because they could proceed instead under a general negligence theory pursuant to Civil

Code section 1714, subdivision (a) (section 1714), which establishes a default duty requiring all persons and entities to exercise reasonable care to avoid causing harm to others. In adopting that view, the court rejected Gilead's contention that a drug manufacturer's only duty under our precedent is the duty to market products free from defects. (*Gilead Tenofovir Cases,* at pp. 922, 934.)

Although the Court of Appeal correctly explained that section 1714 establishes the baseline duty to exercise reasonable care to avoid injuring others, what constitutes reasonable care in a particular context may be defined by statutes, regulations, or judicial decisions. (*Parsons v. Crown Disposal Co*. (1997) 15 Cal.4th 456, 461 (*Parsons*); *Ramirez v. Plough, Inc*. (1993) 6 Cal.4th 539, 547.) This case concerns a drug manufacturer's duty to prevent harm arising from the use of its products. Decades of products liability precedent have defined that duty as limited to designing, manufacturing, and marketing products that are free from defects. (*Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110, 125 (*Trejo*); *Merrill v. Navegar, Inc*. (2001) 26 Cal.4th 465, 478–479 (*Merrill*).) That precedent lends support for Gilead's view that a manufacturer's duty of reasonable care under section 1714 is limited to designing, manufacturing, and marketing products that are free from defects, such that a manufacturer cannot be held liable for injuries caused by a nondefective product.

Moreover, holding that manufacturers owe a broader duty to not unduly delay developing and commercializing an allegedly safer product to replace a concededly nondefective one could conceivably upend current products liability law. Instead of having to prove that a product is defective — an essential element of any products liability claim, whether sounding in

negligence or strict liability — plaintiffs would need only to convince a fact finder that the manufacturer acted unreasonably in its development and commercialization decisions. This theory of negligence liability lacks a clear limiting principle and raises serious questions about whether a workable standard for assessing the reasonableness of such decisions could ever be established. It also risks inviting fact finders to second-guess complex resource-allocation decisions about whether and when to pursue potential alternative products while a concededly nondefective product remains on the market. The prospect of second-guessing presents particularly acute concerns in the prescription drug context, where safety and efficacy assessments are often provisional and uncertain during early stages of clinical research.

We need not, however, definitively determine whether a drug manufacturer may ever be liable in tort for negligent conduct that results in injuries from taking a nondefective drug. Even if we were to assume arguendo that manufacturers may owe a general duty of reasonable care apart from their duty to market products free from defects, we held in *Rowland v. Christian* (1968) 69 Cal.2d 108 (*Rowland*) that foreseeability and policy considerations may justify an exception to section 1714's default duty in appropriate circumstances. Such circumstances exist here.

Where, as here, the allegedly safer drug has not yet undergone large-scale clinical testing in humans or received approval from the federal Food and Drug Administration (FDA), any harm resulting from a drug manufacturer's delay in commercializing that drug would arise, if at all, only through a chain of uncertain scientific outcomes and discretionary decisions by actors beyond the manufacturer's control.

Imposing a duty of care in these circumstances would place extraordinary burdens on drug manufacturers by effectively requiring them to commit substantial time, expenses, and resources to conduct the later-stage clinical trials necessary to obtain FDA approval. It would also risk distorting research priorities and chilling pharmaceutical innovation in ways that may ultimately undermine, rather than advance, public health and safety.

We accordingly hold that, even assuming drug manufacturers owe a broader duty of care apart from their duty to design, manufacture, and market nondefective drugs, the *Rowland* factors compel an exception to such a duty.

I. BACKGROUND

Before providing the factual background of Gilead's development of the drugs at issue, it is helpful to briefly outline the regulatory framework governing the testing and approval of new prescription drugs. Under the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 301 et seq.), a drug manufacturer must gain approval from the FDA before marketing any new drug. New drugs are initially studied in the laboratory and tested in animals to evaluate toxicity and determine whether they can be safely administered to humans in clinical trials. (See 21 C.F.R. § 312.23(a)(8) (2022); FDA, The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective (Nov. 24, 2017) <https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective> [as of August 3,

2026] (hereafter Drug Review Process).)[1] If these preclinical studies yield favorable results, the manufacturer may submit an investigational new drug application (IND) with the FDA to obtain authorization to begin human clinical trials. (See generally 21 C.F.R. § 312.1 et seq. (2022); see also Drug Review Process, *supra*.)

Human testing generally proceeds in three phases. Phase I trials typically involve administering a new drug to a small group of healthy volunteers or patients with the targeted condition — typically between 20 and 80 individuals — to collect preliminary data on safety, tolerability, and appropriate dosage. (21 C.F.R. § 312.21(a) (2022); FDA, The Drug Development Process, Step 3: Clinical Research (Jan. 4, 2018) <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research> [as of August 3, 2026] (hereafter Step 3: Clinical Research).) Phase I trials are intended "to identify rudimentary product characteristics, such as how the body metabolizes a drug and how long it stays in the body, and to provide evidence that the product is not too toxic for further human testing." (FDA, 22 Case Studies Where Phase 2 and Phase 3 Trials had Divergent Results (Jan. 2017) p. 2 (hereafter 22 Case Studies) <https://www.fda.gov/media/102332/download> [as of August 3, 2026].) The FDA estimates that approximately 70 percent of drugs tested in phase I advance to phase II. (Step 3: Clinical Research, *supra*.)

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[1] All Internet citations in this opinion are archived by year, docket number, and case name at <https://courts.ca.gov/opinions/cited-supreme-court-opinions>.

Phase II trials test the drug on up to several hundred subjects who have the targeted condition, with the goal of evaluating efficacy and identifying common short-term side effects and risks. (21 C.F.R. § 312.21(b) (2022); Step 3: Clinical Research, *supra*.) These trials "are intended to explore the effectiveness of the product for a particular indication over a range of doses, and to assess short-term side effects." (22 Case Studies, *supra*, at p. 2.) They "often measure laboratory values or other biomarkers rather than clinical outcomes (i.e., effects on how a patient feels, functions, or survives)." (*Ibid.*) When clinical outcomes are assessed in phase II trials, "it is usually for relatively short periods of time and in a relatively small number of people." (*Id.* at p. 3.) Only about 33 percent of drugs tested in phase II advance to phase III. (Step 3: Clinical Research, *supra*.)

Phase III trials enroll several hundred to several thousand subjects and are conducted over one to four years to obtain the additional information on safety and efficacy necessary to evaluate the drug's overall benefit-risk profile. (21 C.F.R. § 312.21(c) (2022); Step 3: Clinical Research, *supra*.) These trials "generally assess clinical outcomes, and are designed to determine whether the demonstrated benefits of the product outweigh its risks." (22 Case Studies, *supra*, at p. 3.) Because phase III studies are larger and longer in duration, they "provide most of the safety data" and are more likely to reveal long-term or rare side effects. (Step 3: Clinical Research, *supra*.) Even at this stage, only approximately 25 to 30 percent of drugs will be considered successful enough to present results to the FDA for approval. (*Ibid.*) After completing clinical trials, drug manufacturers may file a New Drug Application (NDA) with the FDA and, if approved, may begin marketing the new drug. (See

generally 21 C.F.R. § 314.1 et seq. (2022); see also 21 C.F.R. § 314.105(a) (2022); Drug Review Process, *supra*.)

Gilead followed this regulatory framework in obtaining approval to market tenofovir disoproxil fumarate (TDF) and tenofovir alafenamide fumarate (TAF), both of which are used to treat human immunodeficiency virus (HIV). In 1991, Gilead obtained the exclusive right to develop, manufacture, and sell tenofovir-based medications for the treatment of HIV. Prior to this time, HIV had a 95 percent fatality rate. Tenofovir-based medications such as TDF and TAF would eventually become a cornerstone of HIV antiretroviral therapies, which save millions of lives worldwide each year, as well as a staple in pre-exposure prophylaxis therapies used to prevent HIV infections. (See Ustianowski & Arends, *Tenofovir: What We Have Learnt After 7.5 Million Person-Years of Use*, Infectious Diseases and Therapy (June 2, 2015) vol. 4, pp. 145–146, <https://link.springer.com/article/10.1007/s40121-015-0070-1> [as of August 3, 2026]; FDA, The History of FDA's Role in Preventing the Spread of HIV/AIDS (Mar. 14, 2019) <https://www.fda.gov/about-fda/fda-history-exhibits/history-fdas-role-preventing-spread-hivaids> [as of August 3, 2026].)

In March of 1997, after conducting preclinical research on TDF, Gilead filed an IND with the FDA to obtain approval for human clinical testing of its first TDF-based medication, which would eventually be called Viread. After four years of clinical research of TDF's safety in humans, Gilead filed an NDA for Viread in April 2001, which the FDA approved in October 2001. Gilead subsequently obtained FDA approval to market other TDF-based medications.

Around the same time that it was conducting clinical testing on TDF, Gilead began investigating TAF as a potential backup to TDF. In November 2001, just one month after obtaining FDA approval to market Viread, Gilead filed an IND to begin human clinical testing of TAF. Gilead then conducted a 14-day combined phase I/II clinical trial with 30 subjects — 20 receiving TAF and 10 receiving TDF — to make initial comparisons of the safety and effectiveness of TAF relative to TDF. Plaintiffs contend that this study confirmed what Gilead had already learned in its preclinical research: TAF could achieve the same antiviral effect as TDF at a significantly lower dosage, meaning it was as effective as TDF but with considerably reduced risks of renal, bone, and tooth injuries. Plaintiffs allege that, even though Gilead was aware that TAF was safer than TDF, it announced in 2004 that it had ceased developing TAF because its safety, tolerability, and efficacy profile did not appear sufficiently different from TDF. Plaintiffs claim that this explanation was pretextual and that Gilead discontinued TAF development because it believed TAF would cannibalize TDF's sales. According to plaintiffs, Gilead chose to wait until TDF's patent expired before bringing TAF to market in order to maximize profits on both drugs.

Gilead disputes that it knew TAF was safer than TDF when it chose to discontinue TAF development, or even that it could have known TAF was safer prior to conducting phase III clinical trials. It also challenges plaintiffs' assertion that it delayed TAF development solely to maximize profits. After the Court of Appeal requested supplemental briefing on Gilead's knowledge about TAF's safety relative to TDF, Gilead argued before this court that, had TAF shown "meaningful improvement" over TDF in the combined phase I/II clinical trial,

it would have gone "all-in on TAF" because, although it expected TAF to " 'cannibalize' TDF's market share," it also anticipated that TAF could attract new patients if superior to TDF, yielding "an extra $1 billion over expected TDF revenues between 2008 and 2013." But because TAF did not demonstrate superiority to TDF, Gilead saw no reason to rush it to market: TAF "would only 'cannibalize Viread' *without* helping current patients or attracting new ones," and Gilead "would see no added revenue." Gilead asserts that it later resumed TAF development "to address a new problem": "People were living longer with HIV than anyone dared to hope, and with age comes bone-density loss and reduced kidney function, the same rare side effects associated with TDF." It decided to further explore TAF "on the chance that it might prove to be a lower-dose alternative for that aging population," though its researchers "expressed continued uncertainty that TAF was any safer than TDF."

Plaintiffs concede that the preclinical and clinical data Gilead possessed on TAF in 2004 — including the results of the phase I/II clinical trial — were insufficient to obtain FDA approval or bring TAF to market. Plaintiffs nonetheless claim that Gilead unreasonably delayed taking the steps necessary to commercialize TAF, including conducting the larger-scale human clinical trials required for FDA approval, and that this decision breached a duty of care to them.

Gilead resumed TAF development in 2010. It conducted its first phase III clinical trial on TAF in 2013, and it ultimately obtained FDA approval for TAF in November 2015. 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 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.

At the time Gilead moved for summary judgment, only two claims remained: negligence and fraudulent concealment. The trial court denied Gilead's motion. Gilead then petitioned for writ of mandate, and the Court of Appeal issued an order to show cause. (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 917.) The court ultimately granted the petition in part and denied it in part, directing the trial court to grant summary adjudication as to the fraudulent concealment claim but leaving intact the trial court's denial of summary adjudication on the negligence claim. (*Ibid.*) 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." (*Ibid.*) 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. (*Gilead Tenofovir Cases*, at p. 917.)

We granted review.

II. DISCUSSION

A. Standard of review

In reviewing a denial of summary judgment, we usually apply a de novo standard of review and consider " ' "all the evidence set forth in the moving and opposing papers except that to which objections were made and sustained." ' " (*Yanowitz v. L'Oreal USA, Inc*. (2005) 36 Cal.4th 1028, 1037.) Here, however, the Court of Appeal accepted the allegations of the complaint as true on certain issues — including Gilead's alleged knowledge that TAF was safer than TDF and its profit motivations — reasoning that Gilead "did not contest those assertions for the purposes of the summary judgment motion presently under review." (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at pp. 921–922; see also *American Airlines, Inc. v. County of San Mateo* (1996) 12 Cal.4th 1110, 1118 ["When a motion for summary judgment is used to test whether the complaint states a cause of action, the court will apply the rule applicable to demurrers and accept the allegations of the complaint as true"].) Gilead contends that the Court of Appeal applied the wrong standard of review and that the court should have considered evidence it believes undermines plaintiffs' assertions regarding its knowledge and motivations.

Although Gilead assumed the truth of plaintiffs' allegations for purposes of summary judgment, that assumption must be understood in context. Gilead moved for summary judgment solely on the ground that a negligence claim based on injuries caused by a nondefective product is not cognizable. The

question Gilead believed it was litigating — whether a plaintiff must prove that the injury-causing product was defective — was a pure question of law to which Gilead's knowledge regarding the safety and efficacy of TAF was irrelevant.

The issue changed before the Court of Appeal. After oral argument, the court sua sponte requested supplemental briefing on several issues, including whether plaintiffs contend that Gilead knew or reasonably should have known that TAF was a safer alternative, what plaintiffs must prove Gilead knew or reasonably should have known about TAF relative to TDF to establish a duty to continue developing TAF, and whether the *Rowland* factors require establishing an exception to any such duty. In its eventual opinion, the court rejected Gilead's argument that a drug manufacturer cannot be held liable for injuries resulting from a nondefective product and held that a manufacturer owes a general duty of reasonable care to users of a nondefective drug when deciding whether and when to commercialize an alternative drug it allegedly knows is safer and equally effective. (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 922.) Once the Court of Appeal framed the duty in those terms, knowledge became central to the question of liability.

Given that shift, and because the *Rowland* analysis must be conducted at a " 'categorical' " rather than a " 'case-specific' " level (*Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1021 (*Kuciemba*)), we find it appropriate to consider whether *any* drug manufacturer could reliably know during the early stages of clinical testing that a drug in development is safer than an existing one.

B. Negligence without proof of a defect

In the products liability context, it is well settled that manufacturers have a duty to market products free from defects in design, manufacture, or labeling. (*Trejo*, *supra*, 13 Cal.App.5th at p. 125.) For products other than prescription drugs, California law eases a plaintiff's burden by imposing strict liability for design defects without requiring proof of negligence. (*Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413, 431 (*Barker*).) A plaintiff may alternatively bring a claim for negligent design, manufacture, or labeling of a product (*Jiminez v. Sears, Roebuck & Co.* (1971) 4 Cal.3d 379, 387), and must do so when alleging a prescription drug is defectively designed (*Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1061, 1065 (*Brown*)), but such claims still require proof that the manufacturer's negligence resulted in a defective product (*Jiminez*, at p. 383; *Merrill, supra,* 26 Cal.4th at pp. 478–479).

Against this backdrop, Gilead argues that the product defect requirement limits the scope of a drug manufacturer's default duty of reasonable care established by section 1714, such that a manufacturer cannot be held liable in negligence for injuries caused by a nondefective product. Plaintiffs, by contrast, contend that section 1714 imposes liability for negligent conduct that creates a risk of harm even when the injury-causing product is not defective. The Court of Appeal agreed with plaintiffs. For the reasons discussed below, we have significant doubts regarding plaintiffs' theory of liability. But even assuming plaintiffs' theory is legally viable and that a manufacturer may owe a duty of care under section 1714 for

injuries caused by a nondefective product, the *Rowland* factors justify an exception to any such duty in this context.

Before turning to those factors, we offer some preliminary observations as to why recognizing a duty untethered to a product defect would be difficult to reconcile with settled products liability principles. Plaintiffs are correct that, absent a statutory or judicial exception, all persons and entities are subject to section 1714's rule that everyone is responsible for injuries "occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person." (§ 1714, subd. (a).) In other words, persons and entities are generally " ' "liable for injuries caused by [their] failure to exercise reasonable care in the circumstances" ' " of a given case. (*Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 771 (*Cabral*).) "[T]he law imposes a general duty of care on a defendant only when it is the defendant who has ' "created a risk" ' of harm to the plaintiff, including [situations in which] ' "the defendant is responsible for making the plaintiff's position worse." ' " (*Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 214 (*USA Taekwondo*).) The relevant inquiry is not whether the defendant committed or omitted a particular act, but rather " 'whether the actor's entire conduct created a risk of harm.' " (*Id.* at p. 215, fn. 6.)

We have long recognized, however, that this default duty may be refined and limited in particular contexts through judicial decisions defining the "proper conduct of a reasonable person under particular situations." (*Satterlee v. Orange Glenn School Dist.* (1947) 29 Cal.2d 581, 587; accord, *Kentucky Fried Chicken of Cal., Inc. v. Superior Court* (1997) 14 Cal.4th 814, 824.) In the products liability context, our decisions have generally defined a manufacturer's duty under section 1714 as

the duty to design, manufacture, and market products that are free from defects. Recognizing a broader duty under which liability may arise even absent a defect in the injury-producing product would create substantial tension with that body of law.

To explain, products liability law employs specific tests to determine whether a product is defective. Under the risk-benefit test for design defects, the fact finder weighs the gravity and likelihood of the danger posed by the design against the feasibility, cost, and potential drawbacks of a safer alternative design. (*Barker*, *supra*, 20 Cal.3d at pp. 430–431.) Likewise, a plaintiff alleging a product defect stemming from a failure to warn must establish that the manufacturer knew or had reason to know the product was dangerous for its intended use, had no reason to believe users would recognize the danger, and failed to exercise reasonable care to provide an adequate warning. (*Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 64.) Regardless of the governing test, liability turns on whether the product is defective. (*Merrill*, *supra*, 26 Cal.4th at pp. 479–480.)

Plaintiffs' theory risks circumventing these settled principles. If manufacturers owed a broader duty to act reasonably to avoid all product-related injuries, plaintiffs could seek recovery for harms caused by concededly nondefective products merely by alleging the manufacturer acted unreasonably. Questions currently governed by established defect tests would instead be left to a fact finder's generalized assessment of reasonableness.

This problem is especially acute in the context of prescription drug development. A generalized negligence standard would invite fact finders to second-guess complex research, development, and resource-allocation decisions made

under conditions of scientific uncertainty and incomplete information, including decisions regarding whether and when to pursue potential alternative drugs while a concededly nondefective drug remains on the market. Unlike product defect claims, which are evaluated based on contemporaneous and relatively complete scientific evidence available at the time of the product's distribution (see *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1116 (*Carlin*)), evaluating the reasonableness of drug-development decisions would require retrospective assessment of inherently provisional judgments made based on evolving scientific data.

Perhaps recognizing these difficulties, the Court of Appeal attempted to narrow the duty by limiting it to situations in which a drug manufacturer has already invented or developed a drug it knows to be safer and equally effective. (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at pp. 922, 944.) Although the Court of Appeal purported to select the term " 'invent' " rather than " 'develop,' " on the ground that "the meaning of 'develop' in the pharmaceutical context is ambiguous" (*id.* at p. 921, fn. 3), it later described the duty as requiring a manufacturer to act with reasonable care when it has "*developed* an alternative that it knows is safer and at least equally efficacious" (*id.* at p. 944, italics added). Both terms are ambiguous and, for that reason, are unlikely to act as meaningful constraints in practice.

For example, what does it mean for a drug to be "invented"? Does invention occur when the compound is first conceived, or when it is synthesized in a laboratory, or when it is tested in animals or humans? The term "developed" may suggest a later stage in the multistep, highly regulated process of bringing a drug to market, yet it likewise lacks a clear limiting

principle. Does development occur after early clinical studies, or only after large-scale clinical trials are completed? The absence of any clear limiting principle illustrates the difficulty of imposing negligence liability untethered from traditional defect-based principles.

The same uncertainty surrounds the Court of Appeal's requirement that the manufacturer "know[]" the alternative drug is safer than and as effective as the existing drug. (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 922.) This requirement contemplates not only knowledge that the alternative drug is safe and effective, but also comparative knowledge that it is both safer and at least as effective as the existing drug. The court accepted as true plaintiffs' allegations that Gilead possessed such knowledge based on a single phase I/II clinical trial comparing TAF to TDF — a study lasting only two weeks and involving just 30 subjects. But that conclusion rests on a flawed premise; namely, that a drug can be sufficiently developed, and its safety and efficacy sufficiently known, before completion of phase III clinical trials and FDA approval. That premise is inconsistent with the statutory and regulatory framework governing drug development. It also underscores the difficulty of imposing negligence liability based on preliminary and evolving safety assessments of an alternative drug still under development, rather than on a defect in the drug currently being sold.

As the highly regulated drug development process makes clear, drugs that appear promising in phase I or phase II trials may later prove less effective than anticipated or may reveal previously undetected adverse effects when studied over longer periods and in larger, more diverse patient populations. (See Step 3: Clinical Research, *supra*; 22 Case Studies, *supra*, at p. 2.)

The FDA cautions that early-stage trials may fail to detect less common or long-term side effects, and that phase III trials are more likely to uncover such risks because of their size and duration. (Step 3: Clinical Research, *supra*.) As one amicus curiae observes, positive early-phase results are better understood as a basis for continued testing than as reliable confirmation that a drug is safe, effective, or likely to obtain regulatory approval. Moreover, even if an alternative drug ultimately proves safer than an existing one for some patients, it may present different or offsetting risks for others, further undermining the premise that a manufacturer could reliably "know" during early-stage development that an alternative drug is categorically safer and equally effective for all users.[2]

Federal law reinforces this point. Under the FDCA, the FDA may not approve a new drug absent " 'substantial evidence' " of safety and efficacy, defined as "evidence consisting of adequate and well-controlled investigations, including clinical investigations." (21 U.S.C. § 355(d).) The FDA has interpreted this requirement to mean, in the ordinary case, "at least two adequate and well-controlled studies" — typically phase III clinical trials — demonstrating both safety and efficacy. (FDA, Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (May

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[2] The dissent asserts that "plaintiffs' claim is based on a duty that exists in the latter stages of development." (Dis. opn. of Evans, J., *post*, at p. 9.) That description is difficult to reconcile with the record. Plaintiffs contend Gilead acted unreasonably after completing a two-week initial phase I/II clinical trial involving only 30 subjects (only 20 of whom received TAF), with approximately five additional years of clinical testing, regulatory review, and commercialization efforts remaining before TAF ultimately reached the market.

1998) p. 3 (hereafter Guidance for Industry) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-clinical-evidence-effectiveness-human-drug-and-biological-products> [as of August 3, 2026]; see also, 22 Case Studies, *supra*, at p. 2 ["Typically, a candidate drug is submitted to the FDA for marketing approval after phase 3 testing"].) Although the agency may, in limited circumstances, rely on a single trial with confirmatory evidence, that exception underscores the general rule rather than displacing it. (See Guidance for Industry, at p. 3.) Consistent with this framework, manufacturers are prohibited from making claims about a new drug's safety or efficacy prior to FDA approval; such claims would be treated as false or misleading statements. (21 U.S.C. § 352(n) & (gg)(1)(B)(i)(II); 21 C.F.R. § 202.1(e)(6)(i)–(ii), (xvi) (2022).) The statutory and regulatory scheme thus reflects the understanding that definitive judgments regarding a drug's risks and benefits ordinarily cannot be made before completion of phase III trials and FDA approval. The Court of Appeal's knowledge requirement is therefore largely unattainable during the early stages of development, as TAF was during the relevant period here. That conclusion reinforces our doubt that liability may be imposed under section 1714 for injuries caused by a concededly nondefective drug based on allegedly unreasonable development decisions regarding a different, unapproved drug.

The Court of Appeal believed that our decision in *Mexicali Rose v. Superior Court* (1992) 1 Cal.4th 617 "effectively resolve[d]" the issue by holding that a negligence claim may proceed against a manufacturer absent a product defect. (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 926.) In *Mexicali Rose*, we held restaurants must "exercise reasonable

care in the preparation of [their] food" even where the food itself is not defective. (*Mexicali Rose*, at p. 633.) But that holding arose in the unique context of food preparation. Prepared food may contain natural substances — there, a chicken bone — that are inherent in food yet potentially dangerous when present in a size, shape, or quantity capable of causing injury when consumed. (*Id.* at p. 632.) Although it would make little sense to characterize such natural substances as "defects" in the food, it does make sense to require restaurants to exercise reasonable care in removing them once they pose a sufficient danger. Reflecting the narrow basis for our holding, we expressly limited it "to commercial restaurant establishments." (*Id*. at p. 619, fn. 1.) That context is far removed from prescription-drug development. Thus, *Mexicali Rose* does not stand for the broader principle that manufacturers may be liable in negligence for injuries resulting from nondefective products.

For these reasons, we have substantial doubt that California law recognizes a general negligence duty requiring drug manufacturers to act reasonably in making drug-development and commercialization decisions apart from their established duty to design, manufacture, and market products free from defects. Products liability law has long tied a manufacturer's duty of care to defects in the product placed into the stream of commerce, and plaintiffs identify no clear limiting principle for imposing liability absent proof of a product defect.

While we are skeptical that the duty plaintiffs propose is consistent with products liability law as it has developed to this point, we are cognizant that tort law is a broad and ever-developing area of law. In this case, we need not definitively decide whether the defect requirement categorically limits the scope of a manufacturer's general duty of reasonable care under

section 1714 in all circumstances. Even assuming a broader duty could exist in some circumstances, plaintiffs' theory — that Gilead owed them a duty to make reasonable development and commercialization decisions regarding TAF — is not cognizable in light of the foreseeability and public policy considerations identified in *Rowland*, *supra*, 69 Cal.2d at page 113. We turn to the *Rowland* factors below.

C. Duty of care

In *Rowland*, we identified several considerations that may justify a judicial exception to section 1714's duty of care. (*Rowland*, *supra*, 69 Cal.2d at pp. 112–113.) These considerations fall into two categories. The foreseeability factors evaluate "the foreseeability of harm to the plaintiff," as well as related concerns such as "the degree of certainty that the plaintiff suffered injury" and "the closeness of the connection between the defendant's conduct and the injury suffered." (*Id.* at p. 113; accord, *Kuciemba*, *supra*, 14 Cal.5th at p. 1021.) The public policy factors examine "the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost, and prevalence of insurance for the risk involved." (*Rowland*, at p. 113; accord, *Kuciemba*, at pp. 1021–1022.)

Different timeframes apply to the two sets of factors. (*Kuciemba*, *supra*, 14 Cal.5th at p. 1022.) The foreseeability factors "are assessed based on information available during the time of the alleged negligence," whereas policy considerations — such as the burdens imposed on defendants — are forward-looking. (*Ibid.*) Both the foreseeability and the public policy

factors are analyzed " 'at a relatively broad level of factual generality' " to determine not whether an exception is warranted in the specific circumstances of a particular case, but rather " 'whether carving out an entire category of cases from that general duty rule is justified by clear considerations of policy.' " (*Id.* at p. 1021.) In short, " 'the duty analysis is categorical, not case specific.' " (*Ibid.*)

Nevertheless, while the *Rowland* factors are analyzed at a categorical level rather than based on case-specific facts, we may properly consider the general circumstances regarding the development process for TAF — including the steps Gilead needed to take to bring TAF to market — in determining whether manufacturers in similar positions should owe a duty of care to users of an existing drug when deciding whether and when to commercialize an alternative drug. We do not, however, consider Gilead's particular internal deliberations, resource constraints, or other case-specific factors that may have influenced its decision regarding whether and when to commercialize TAF. Such fact-bound considerations are not part of the court's duty analysis and are instead properly reserved for the fact finder in determining whether a duty was breached.

We analyze the *Rowland* factors to determine whether foreseeability and public policy considerations warrant an exception to any duty of reasonable care a drug manufacturer may otherwise owe to users of a nondefective drug when

developing and deciding whether to commercialize a potentially safer alternative.

1. Foreseeability Factors

Of the three foreseeability factors — foreseeability, certainty, and the closeness of the connection between the defendant's conduct and the injury — the most important is the first one; that is, "whether the injury in question was foreseeable." (*Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1145 (*Kesner*).) Our task " 'is not to decide whether a *particular* plaintiff's injury was reasonably foreseeable in light of a *particular* defendant's conduct, but rather to evaluate more generally whether the category of negligent conduct at issue is sufficiently likely to result in the kind of harm experienced that liability may appropriately be imposed.' " (*Cabral*, *supra*, 51 Cal.4th at p. 772.) We therefore consider whether it was reasonably foreseeable that a drug manufacturer's decision to delay taking the steps necessary to develop and commercialize an allegedly safer drug would result in harm to users of the existing drug. Because almost any harm can be described as foreseeable after the fact, our analysis focuses on whether such harm was reasonably foreseeable to the manufacturer at the time it chose to delay developing and commercializing the new drug. To do otherwise would risk hindsight bias, since " 'with hindsight, everything is foreseeable.' " (*Colonial Van & Storage, Inc. v. Superior Court* (2022) 76 Cal.App.5th 487, 503; accord, *Vasilenko v. Grace Family Church* (2017) 3 Cal.5th 1077, 1088 (*Vasilenko*).)

The Court of Appeal concluded that this factor did not support recognizing an exception to the duty of care based on the premise that a drug manufacturer is capable of knowing,

before completing phase III clinical trials and obtaining FDA approval, that an alternative drug is both safer than and as effective as an existing drug. (See *Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at pp. 937, 945–948.) But as explained above, the difficulty of making comparative judgments, the structure of the drug-approval process, and the governing statutory and regulatory framework demonstrate that such knowledge ordinarily cannot be established at earlier stages of development.

Early clinical studies are preliminary and provide only limited, provisional information about a new drug's safety and effectiveness. Phase I trials involve small numbers of healthy volunteers or patients with the targeted condition and are designed primarily to assess basic safety, tolerability, and dosage information, rather than overall therapeutic benefits and risks. (21 C.F.R. § 312.21(a) (2022); Step 3: Clinical Research, *supra*; 22 Case Studies, *supra*, at p. 2.) Phase II trials expand testing to a somewhat larger group of patients with the targeted condition, but they remain exploratory in nature and focus primarily on short-term side effects rather than long-term safety. (21 C.F.R. § 312.21(b) (2022); Step 3: Clinical Research, *supra*; 22 Case Studies, *supra*, at p. 2.) The results of these studies may appear promising, only for further research to reveal previously unknown long-term or rare side effects that may cause the new drug's risks to outweigh its benefits. (Step 3: Clinical Research, *supra*; 22 Case Studies, *supra*, at p. 3.)

Indeed, according to the FDA, only about one-third of drugs evaluated in phase II clinical trials yield results promising enough to proceed to phase III testing. (Step 3: Clinical Research, *supra*.) And only about 25 to 30 percent of drugs that advance to phase III trials are considered successful

enough to undergo further testing or to present results to the FDA for approval. (*Ibid.*) Drugs that appear promising in phase I or phase II trials may later prove less effective than anticipated or reveal previously undetected adverse effects when studied for a longer period in larger and more diverse patient populations. (See Step 3: Clinical Research, *supra*; 22 Case Studies, *supra*, at p. 2.) Consistent with this understanding, the FDCA requires "substantial evidence" of safety and efficacy, generally from at least two adequate and well-controlled studies — typically phase III clinical trials — before a drug may receive FDA approval. (21 U.S.C. § 355(d); Guidance for Industry, *supra*, at p. 3.) Manufacturers may not represent an investigational drug as safe or effective before FDA approval. (21 U.S.C. § 352(n) & (gg)(1)(B)(i)(II); 21 C.F.R. § 202.1(e)(6)(i)–(ii), (xvi) (2022).)

The dissent adopts an approach that effectively removes this inquiry from the court's purview by asserting that the knowledge question must be reserved for the fact finder. (Dis. opn. of Evans, J., *post*, at p. 15.) But *Rowland* requires courts to determine, as a matter of law, whether drug manufacturers as a class could reasonably know, based on only early-phase clinical trials, that an alternative drug is safer than an existing one such that pausing the alternative drug's development would foreseeably harm users of the existing drug. The very purpose of *Rowland*, which our courts have now applied for almost 60 years, is to allow courts — not a jury — to make a legal determination as to whether liability can attach at all. If the relevant knowledge inquiry were invariably reserved for the fact finder, courts could never meaningfully assess foreseeability

based on "information available during the time of the alleged negligence." (*Kuciemba*, *supra*, 14 Cal.5th at p. 1022.)

For these reasons, the Court of Appeal erred in concluding 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. (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 938.) 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.

The second foreseeability factor is "the degree of certainty that the plaintiff suffered injury." (*Rowland*, *supra*, 69 Cal.2d at p. 113.) This factor applies " 'primarily, if not exclusively, when the only claimed injury is an intangible harm, such as emotional distress,' " because such harms can be uncertain or difficult to verify. (*Kuciemba*, *supra*, 14 Cal.5th at p. 1023.) Here, plaintiffs' personal injury claims "are both tangible and amenable to compensation." (*Ibid.*) Because plaintiffs allege concrete physical injuries that are readily compensable, this factor does not support recognizing an exception to a duty of care.

The third foreseeability factor requires us to examine "the closeness of the connection between the defendant's conduct and the injury suffered." (*Rowland*, *supra*, 69 Cal.2d at p. 113.) "[W]here the injury suffered is connected only distantly and

indirectly to the defendant's negligent act, the risk of that type of injury from the category of negligent conduct at issue is likely to be deemed unforeseeable." (*Cabral*, *supra*, 51 Cal.4th at p. 779.) This factor therefore requires an examination of the causal connections between the alleged negligence and the injury, an inquiry "akin to analyzing proximate causation." (*Kuciemba*, *supra*, 14 Cal.5th at p. 1024.) In addition, it "accounts for third party or other intervening conduct" that is independent of, and not derivative of, the defendant's negligence. (*Vasilenko*, *supra*, 3 Cal.5th at p. 1086.)

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. (See, e.g., *Vasilenko*, *supra*, 3 Cal.5th at p. 1086 [a church's directions to park across a public street bore only an attenuated relationship to an injury resulting from the independent decisions by the plaintiff and a third party driver]; *State Dept. of State Hospitals v. Superior Court* (2015) 61 Cal.4th 339, 355–356 (*State Hospitals*) [no proximate causation where the injury depended on a speculative chain of discretionary third party decisions, including a third party evaluator's determination as to whether the injury-causing actor was a sexually violent predator].) 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.

First, as explained above, early clinical studies provide only preliminary and incomplete information regarding a drug's safety and efficacy, and drugs that initially appear promising

may later prove ineffective or reveal previously undetected adverse effects during phase III trials involving larger and more diverse patient populations. (See Step 3: Clinical Research, *supra*; 22 Case Studies, *supra*, at p. 2.) Thus, any causal connection between a drug manufacturer's decision to pause or discontinue development of an alternative drug after having completed only early-phase clinical testing and a plaintiff's later injury from an existing drug may be severed if the alternative drug ultimately fails in phase III trials.

Second, if the manufacturer decides to proceed to phase III testing and the results of such testing are promising, the drug may nevertheless fail to obtain FDA approval. (See Sacks et al., *Scientific and Regulatory Reasons for Delay and Denial of FDA Approval of Initial Applications for New Drugs, 2000-2012* (Jan. 2014) 311 JAMA 4 (hereafter FDA Approval) [analyzing cases in which the FDA declined to approve a new drug because it failed to demonstrate superior efficacy or increased safety] <https://jamanetwork.com/journals/jama/fullarticle/1817795> [as of August 3, 2026].) Plaintiffs do not dispute Gilead's assertion that, "of medicines entering clinical trials, fewer than one out of eight will obtain FDA approval." (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 939; see also Step 3: Clinical Research, *supra*; United States Government Accountability Office, Investigational New Drugs: FDA Has Taken Steps to Improve the Expanded Access Program but Should Further Clarify How Adverse Events Data Are Used (July 2017) p. 6 [of the drugs that entered phase I trials, 9.6 percent received FDA approval] <https://www.gao.gov/assets/gao-17-564.pdf> [as of August 3, 2026].)

The Court of Appeal did not find this fact significant, opining that because the asserted duty involves a drug

candidate "the manufacturer knows to be as effective as, and safer than, an existing drug" "FDA approval [is] far less uncertain than might otherwise be the case." (*Gilead Tenofovir Cases*, 98 Cal.App.5th at p. 939.) But again, the court erred in accepting that a drug manufacturer can genuinely know of a new drug's safety and efficacy before completing phase III clinical trials. Moreover, even where a manufacturer goes on to complete phase III trials and, based on the results of those studies, believes that its new drug is promising and likely to obtain FDA approval, the FDA may nevertheless disagree and deny approval. (See FDA Approval, *supra*, 311 JAMA 4.) Thus, a manufacturer's own assessment of a drug's safety and efficacy does not make FDA approval certain. (*Ibid.*)

Third, if the FDA approves the new drug and it is brought to market, a patient's physician may nevertheless decide, in consultation with the patient, that the existing drug is the better option for that individual. The Court of Appeal discounted this possibility, reasoning that "once the FDA has approved an alternative that is safer and at least equally effective for the patient concerned, the manufacturer would reasonably expect doctors to prescribe the new medication in place of the old." (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 939.) That conclusion, however, rests on the assumption that a new drug is a safer and better option than an existing one for *all* patients — an assumption that fails to account for the complexity of prescription drug therapy. Typically, alternative drugs used to treat the same condition present different risks and benefits, making one drug safer for some patients but not necessarily for others. We recognized this reality in *Brown*, where we observed that "the superiority of one drug over another" must be evaluated with respect to each individual plaintiff, "since the

advantages of a drug cannot be isolated from the condition of a particular patient." (*Brown*, *supra*, 44 Cal.3d at p. 1068.) "Thus, in one case the drug that injured the plaintiff might be the better choice, while this would not be true as to another user." (*Ibid.*) Physicians and patients may therefore reasonably differ in their assessments of which drug represents the safer option. For example, a new drug may carry a lower risk of a severe side effect — such as liver failure — while also causing other, less serious but more common side effects, such as weight gain or increased cholesterol. A physician treating a patient concerned about weight gain or high cholesterol might conclude that the existing drug is the better choice, while another physician might determine that the less severe side effects are acceptable risks when weighed against the risk of liver failure.

Indeed, this variability in physician and patient preferences is evident even with respect to TDF and TAF. As plaintiffs conceded in their briefing to the Court of Appeal below, "for a variety of reasons, some physicians and patients prefer TDF over TAF." And while plaintiffs may now believe that they would not have opted to take TDF over TAF given the injuries they allege they ultimately suffered, such retrospective judgments are "prone to hindsight bias." (*Himes v. Somatics, LLC* (2024) 16 Cal.5th 209, 234 [rejecting subjective patient standard for failure-to-warn claims against prescription drug manufacturers due to risk of hindsight bias]; accord, *Cobbs v. Grant* (1972) 8 Cal.3d 229, 245 [rejecting subjective patient standard for informed consent claims due to risk of hindsight bias].)

The dissent fails to engage with this inquiry. Instead, it mischaracterizes our analysis as suggesting that independent decisions by the FDA, physicians, or others "worsened" or

"exacerbated" plaintiffs' injuries (dis. opn. of Evans, J., *post*, at p. 16), when our point is that those intervening decisions render the connection between the alleged conduct and plaintiffs' injuries too remote to make the risk of injury sufficiently foreseeable. (See *Cabral*, *supra*, 51 Cal.4th at p. 779 ["[W]here the injury suffered is connected only distantly and indirectly to the defendant's negligent act, the risk of that type of injury from the category of negligent conduct at issue is likely to be deemed unforeseeable"].) If the alternative drug failed in phase III trials, or was not approved by the FDA, or would not have been prescribed to a plaintiff, then there would be *no* connection between a drug manufacturer's decision to pause development of that drug and any injuries resulting from the use of an existing drug.

For these reasons, and consistent with our prior decisions applying the third foreseeability factor, we conclude that a drug manufacturer's decision to cease taking the steps necessary to develop and bring to market an allegedly safer drug is remote from a plaintiff's injuries caused by an existing drug. (See *Cabral*, *supra*, 51 Cal.4th at pp. 779–780; *Vasilenko*, *supra*, 3 Cal.5th at p. 1086.) Any asserted causal connection depends on a speculative chain of intervening events and discretionary decisions by third parties that are neither foreseeable in any concrete sense nor derivative of the manufacturer's conduct. (See *Vasilenko*, at p. 1086; *State Hospitals*, *supra*, 61 Cal.4th at pp. 355–356.) Those intervening acts include the uncertain outcomes of additional clinical testing, the FDA's independent regulatory judgment whether to approve the new drug, and physicians' individualized prescribing decisions based on patient-specific risk-benefit assessments. These independent and contingent decisions render the connection between the

defendant's conduct and the plaintiff's injury highly attenuated. Accordingly, this factor supports recognizing an exception to any duty a manufacturer might otherwise owe to develop and commercialize an allegedly safer drug.

2. Public Policy Factors

In addition to foreseeability factors, the *Rowland* analysis includes policy considerations which "may dictate a cause of action should not be sanctioned no matter how foreseeable the risk" (*Elden v. Sheldon* (1988) 46 Cal.3d 267, 274), such as where the consequences of recognizing a particular duty of care would create "an intolerable burden on society" (*id.* at p. 277; accord, *Kuciemba*, *supra*, 14 Cal.5th at p. 1025).

The first policy factor is "the moral blame attached to the defendant's conduct." (*Rowland*, *supra*, 69 Cal.2d at p. 113.) Moral blameworthiness is difficult to evaluate categorically in this context because drug manufacturers, as a class, may delay developing and commercializing an alternative drug for a variety of reasons. The Court of Appeal correctly observed that "a manufacturer's decision to delay the commercialization of a safer drug may be made for morally neutral, or even worthy, reasons." (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 942.) As amicus curiae Community Education Group explains, 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 treated by a nondefective drug. Alternatively, a manufacturer 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. Manufacturers' decisions about whether to continue developing or commercializing an alternative drug ordinarily involve competing scientific, medical, regulatory, and business considerations, including resource allocation and commercial viability. Especially in the early phases of drug development, those decisions must be made with limited information about which drug candidates are most likely to succeed.

The Court of Appeal nevertheless concluded — somewhat circuitously — that the moral blame factor favors recognizing a duty of care because the asserted duty attaches only to a drug manufacturer's *negligence* in its decisions about commercializing an allegedly safer drug. (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 942.) But if negligence alone sufficed to establish moral blameworthiness, this factor would invariably favor the imposition of a duty of care in every case, since negligence is alleged in every negligence action. For this reason, "the moral blame that attends ordinary negligence is generally not sufficient to tip the balance of the *Rowland* factors in favor of liability." (*Adams v. City of Fremont* (1998) 68 Cal.App.4th 243, 270, disapproved of on another ground in *USA Taekwondo*, *supra*, 11 Cal.5th 204.) Indeed, we have found little to no moral blameworthiness when a driver had negligently stopped a vehicle alongside a freeway for a nonemergency purpose (*Cabral*, *supra*, 51 Cal.4th at p. 782) and when a church negligently required invitees to park in a lot

across a busy street from the church (*Vasilenko*, *supra*, 3 Cal.5th at p. 1091).

Moral blameworthiness is instead found where the defendant has acted not merely unreasonably but with some degree of moral culpability, such as where it has actual knowledge of a known but hidden danger and fails to take reasonable measures to avert foreseeable harm (see *Peterson v. San Francisco Community College Dist.* (1984) 36 Cal.3d 799, 814); reaps a financial benefit from risks it created (*Kuciemba*, *supra*, 14 Cal.5th at p. 1025); exploits a relative inequality between the parties or exercises greater control over the risks at issue (*id.* at p. 1026); or engages in affirmative misconduct that society seeks to deter (see *Christensen v. Superior Court* (1991) 54 Cal.3d 868, 896–898).

The dissent focuses on plaintiffs' allegations that Gilead deliberately delayed developing and commercializing TAF solely to extend its patent over tenofovir-related medications and maximize its profits. (Dis. opn. of Evans, J., *post*, at pp. 17–19.) But *Rowland* requires us to evaluate moral blame categorically rather than by reference to the precise circumstances and motivations plaintiffs attribute to Gilead in this case. (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 942; see also *id.* at p. 936.) The question is not whether Gilead's alleged reasons for delay were proper or improper, but rather whether the category of conduct alleged ordinarily reflects moral culpability. And although, at a categorical level, profit considerations may be among the many factors drug manufacturers weigh when deciding whether to continue developing and commercializing

an alternative drug, such considerations may be only one among several that guide the decision to delay development.

Citing to our holdings in *Kesner* and *Kuciemba*, the dissent additionally asserts that moral blameworthiness must be found whenever there exists "the reaping of a profit and inherent power imbalance between plaintiffs and defendants." (Dis. opn. of Evans, J., *post*, at p. 18.) But that description applies to virtually every negligence action brought against a business. We do not read *Kesner* and *Kuciemba* so expansively. Although in certain circumstances profit maximization can be characterized as "immoral" in some sense, a manufacturer's decision to delay developing an allegedly safer version of a lifesaving drug solely to increase profits is morally blameworthy only if the manufacturer can reliably know, before later-stage clinical testing and FDA approval, that the alternative drug is in fact safer than the existing one. As explained above, it cannot.

Finally, assuming a drug manufacturer could know — prior to phase III testing and FDA approval — that an alternative drug is safer than an existing one, and further assuming manufacturers would categorically decide to delay commercializing alternative drugs only to maximize profits, we have explained that moral blameworthiness depends upon whether "there were reasonable ameliorative steps the defendant could have taken . . . 'to avert the foreseeable harm.' " (*Vasilenko*, *supra*, 3 Cal.5th at p. 1091.) For example, in *Parsons, supra,* 15 Cal.4th 456, we concluded that a garbage truck operator had no reasonable means of averting the risk that a horse would be startled by its ordinary operations, because any proposed precautions — including altering collection hours or temporarily blocking the collection area — would be impractical

and socially costly. (*Id.* at p. 474.) Likewise, in *Vasilenko*, we found no moral blame where it was unclear what effective and affordable ameliorative steps a church could take to mitigate the danger posed by requiring invitees to cross a busy street between a parking lot and the church. (*Vasilenko*, at p. 1091.) We noted that, while a landowner could petition relevant authorities to install traffic control devices, such as crosswalks or traffic signals, the ultimate decision rests with those authorities. (*Id.* at p. 1087.)

Similarly, here, the ameliorative steps a drug manufacturer would need to take to develop and bring an alternative drug to market are both resource-intensive and time-consuming, since extensive and costly clinical trials are required to secure FDA approval. Moreover, because the FDA is the ultimate decision maker as to whether a new drug may be marketed, the timing and feasibility of commercializing an alternative drug are not entirely within the manufacturer's control. For these reasons, we conclude that a drug manufacturer's negligent decision to delay developing and commercializing an alternative drug is not categorically morally blameworthy.

The second policy factor is "the policy of preventing future harm." (*Rowland*, *supra*, 69 Cal.2d at p. 113.) This policy "is ordinarily served . . . by imposing the costs of negligent conduct upon those responsible." (*Cabral*, *supra*, 51 Cal.4th at p. 781.) It may be outweighed, however, "by laws or mores indicating approval of the conduct or by the undesirable consequences of allowing potential liability." (*Id.* at p. 782.) Accordingly, this factor "examines both the positive and the negative societal

consequences of recognizing a tort duty." (*Kuciemba*, *supra*, 14 Cal.5th at p. 1026.)

On the one hand, a duty of care in this context could incentivize manufacturers to more promptly develop and commercialize drugs that may prove to be safer than and as effective as existing treatments, thereby preventing harm to some users of those treatments. It is plainly in the public interest for manufacturers to develop and bring to market safer drugs that may reduce injuries to patients already suffering from serious underlying conditions. Here, plaintiffs allege that had they been able to take TAF rather than TDF at an earlier date, they may have avoided serious side effects caused by TDF.

On the other hand, as plaintiffs themselves acknowledge, drug manufacturers already have "ample incentive[s] 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. (See *Vasilenko*, *supra*, 3 Cal.5th at p. 1088 [observing that landowners already have incentives to provide safe and convenient parking].)

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. As amicus curiae Community Education Group explains, 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. Because the proposed duty would attach only to alternative drugs that are purportedly safer than existing therapies — and not to entirely new therapies — a manufacturer would face potential tort liability only if it failed to develop an alternative drug. 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.

Amicus curiae further observes that manufacturers may become reluctant to initiate early clinical studies of backup or alternative drug candidates for fear that those studies could later be used to support negligence claims. Faced with the possibility that a decision to continue developing a lead candidate rather than a backup candidate could later be deemed unreasonable, manufacturers might forgo early-stage research of backup candidates altogether. Alternatively, if manufacturers deem it too risky to wholly forgo researching backup candidates — given the possibility that a lead candidate may fail — they might instead delay commercializing a lead candidate until all potential backup candidates are fully tested in clinical trials.

This Court has previously declined to impose liability rules that would produce precisely these outcomes. In *Brown*, we rejected strict liability for design defects in prescription

drugs, cautioning that "[i]f drug manufacturers were subject to strict liability, they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed," and might instead withhold a drug from the market "until scientific skill and knowledge advanced to the point at which additional dangerous side effects would be revealed." (*Brown*, *supra*, 44 Cal.3d at p. 1063.) Similarly, a duty not to unreasonably delay commercializing alternative treatments could distort manufacturers' decisions regarding whether to continue developing such treatments where preliminary research suggests they may reduce certain risks, but the manufacturers would otherwise elect not to pursue them due to competing concerns or research priorities.

Plaintiffs argue that these concerns are overstated because liability would attach only to *unreasonable* decisions regarding whether and when to commercialize an allegedly safer drug. They contend, for example, that allocating resources to address a more pressing medical need would not be considered unreasonable. That may be true in the abstract, but it would likely prove difficult to evaluate the reasonableness of a drug manufacturer's resource allocation decisions in hindsight. Amicus curiae Pharmaceutical Research and Manufacturers of America explains that drug development frequently involves pursuing multiple potential drug candidates in parallel, with the understanding that many drug candidates will fail. As noted above, plaintiffs do not dispute Gilead's contention that only one out of eight drug candidates entering clinical trials ultimately receives FDA approval. (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 939.) According to amicus curiae, because of this high failure rate, it is standard

industry practice to collect data on backup candidates while proceeding with a lead candidate. During this development process, drug manufacturers must make complex strategic decisions about where to devote finite resources based on limited information. These decisions are often provisional, iterative, and contingent on preliminary laboratory or clinical studies that may later prove incorrect. As a result, they do not readily lend themselves to retrospective evaluations of reasonableness armed with the benefit of hindsight.

To illustrate, a manufacturer might determine, based on early clinical data, that a backup candidate had the potential to reduce certain side effects associated with a lead candidate. The manufacturer may nevertheless discontinue development if it believes patients would prefer the lead drug because of dosing convenience or due to other side effects associated with the backup drug. If the evidence later reveals that those concerns were unfounded and that patients ultimately fared better on the backup drug, a retrospective negligence inquiry could conclude that the manufacturer's initial development decision was unreasonable. When multiple potential alternative drugs exist, moreover, there is no obvious basis for determining whether one development path was more reasonable than another.

As explained above, assessing the reasonableness of a drug manufacturer's research and development decisions differs fundamentally from evaluating product defect claims. Product defect claims are judged based on contemporaneous and relatively complete scientific evidence available at the time of manufacture and distribution. (See *Carlin*, *supra*, 13 Cal.4th at p. 1116.) By contrast, evaluating drug development choices entails a backward-looking assessment of the research priorities a manufacturer adopted based on preliminary and evolving

scientific evidence. This retrospective inquiry creates a substantial risk that hindsight will supplant the manufacturer's contemporaneous judgment, even when its decisions were reasonable when made.

Contrary to the dissent's suggestion, we do not question a fact finder's ability to resolve ordinary negligence claims involving complex scientific evidence, such as negligent design, manufacture, or marketing claims. (Dis. opn. of Evans, J., *post*, at pp. 10–12.) Rather, the *Rowland* inquiry requires us to determine whether this category of conduct should be subjected to negligence liability in the first place. Unlike traditional products liability claims, this novel theory would require fact finders to assess whether a manufacturer acted reasonably in deciding whether and when to continue researching, developing, and commercializing a drug that never completed clinical testing or received FDA approval. That inquiry asks fact finders to reconstruct years of research and development decisions made in the face of evolving scientific evidence and uncertain outcomes, rather than to evaluate the safety of a product that actually reached the market. Neither the plaintiffs nor the dissent have identified a single case wherein a fact finder has been tasked with making such determinations.

In sum, although recognizing a tort duty might reduce injuries for some patients, it also carries a risk of adverse consequences that may not serve public health and safety as a whole. We accordingly conclude that this factor weighs in favor of recognizing an exception to any duty of care a drug manufacturer may otherwise owe in this context.

The third policy factor examines "the extent of the burden to the defendant and consequences to the community of

imposing a duty to exercise care with resulting liability for breach." (*Rowland*, *supra*, 69 Cal.2d at p. 113.) This factor overlaps somewhat with the prior one, insofar as it requires consideration of potential adverse consequences to the community. (*Lorenzo v. Calex Engineering, Inc.* (2025) 110 Cal.App.5th 49, 70; see also *Vasilenko*, *supra*, 3 Cal.5th at p. 1090.)

The asserted duty may undermine, rather than promote, public health and safety by inviting retrospective second-guessing of complex development decisions made under conditions of scientific uncertainty. As Gilead and several amici curiae explain, a manufacturer may develop a highly effective and lifesaving drug and, in the ordinary course of research and development, conduct preliminary studies of backup or alternative candidates — both to pursue potential improvements and to hedge against the substantial risk that any single candidate will fail. If early data on a backup candidate suggests a marginal reduction in certain severe side effects for a limited subset of patients, the asserted duty might expose the manufacturer to significant liability for failing to commercialize that alternative, notwithstanding its limited benefits or offsetting risks. This may create perverse incentives: manufacturers might decline to investigate backup or alternative candidates at all, lest preliminary indications of incremental safety improvements later be used to challenge the reasonableness of their development decisions. That result is especially troubling in the pharmaceutical context where, as Gilead and several amici curiae explain, high clinical-failure rates make parallel development of backup candidates standard practice and essential to avoiding delays in the availability of beneficial medicines if a lead candidate fails. Alternatively,

because liability would only attach once a manufacturer releases a drug, manufacturers may be incentivized to delay commercialization of an otherwise nondefective and potentially lifesaving drug until all backup candidates have been fully explored, slowing patient access while companies search for a hypothetical "perfect" drug.

The asserted duty would also risk interfering with pharmaceutical innovation and the allocation of finite research and development resources more broadly. As Gilead and amicus curiae Community Education Group observe, the duty may encourage manufacturers to focus on making marginal improvements to existing drugs rather than pursuing novel therapies for diseases that lack effective treatment, or to rush to market alternatives that appear safer for some patients but pose greater risks for others. Indeed, the asserted duty may force manufacturers to make an untenable choice: either devote scarce research and development resources to advancing a backup drug to an existing treatment that may reduce the risk of rare side effects for a subset of patients, or risk liability by prioritizing developing a new drug to treat a currently untreatable disease that may prove to be lifesaving for a larger population. More generally, as amicus curiae International Association of Defense Counsel points out, manufacturers could be driven to scour their development histories to identify all conceivable alternative drugs that may reduce risk for any user under any foreseeable circumstance of use, no matter how remote. To avoid liability, manufacturers may then feel pressured to divert limited resources toward commercializing those alternatives, regardless of their overall risk-benefit

profiles or the substantial costs of development and commercialization.

The Court of Appeal rejected these concerns, dismissing Gilead's argument that a duty of care in this context would place manufacturers " 'under an endless obligation to pursue *ever-better* new products or improvements to existing products.' " (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 921.) The court reasoned that the duty merely requires manufacturers to act reasonably in deciding whether to commercialize a drug they have already invented and know to be safer than an existing one. (See *id.* at pp. 921–922, 944.) In reality, however, the duty would likely pressure manufacturers to promptly commercialize all alternative drugs that could later be characterized as safer, even when the existing product is concededly nondefective. Whenever preliminary research suggests that an alternative might reduce certain side effects, a fact finder could be asked to make a backwards-looking determination as to whether the manufacturer acted unreasonably in failing to bring that alternative to market sooner. For the reasons explained above, this duty threatens to skew innovation priorities in a manner that does not advance — and may ultimately undermine — public health and safety.

Moreover, plaintiffs provide no legal basis for confining their theory of liability to the pharmaceutical industry. If manufacturers across all industries owe a general duty of care in making decisions about whether and when to develop and commercialize allegedly safer products, then manufacturers of a wide range of complex consumer products could face liability for their development and commercialization decisions even when the product at issue is otherwise reasonably safe and nondefective. For example, an automobile manufacturer that

does not install particular safety technology — such as lane-change assist or automatic emergency braking — on its vehicles could be exposed to liability for not making the technology available sooner, notwithstanding the fact that its vehicles meet all applicable safety standards and are deemed nondefective under the risk-benefit test. Manufacturers might avoid researching or testing potential safety improvements altogether for fear that preliminary findings might later be used to allege negligence. While we do not decide here whether manufacturers outside of the pharmaceutical context have a duty to commercialize allegedly safer products to replace concededly non-defective ones, we note that accepting plaintiffs' theory of liability could have far-reaching consequences across a broad range of industries.

Not only would a duty of care risk undermining public safety, it would also impose substantial burdens on drug manufacturers. In analyzing this factor, the Court of Appeal focused primarily on Gilead's argument that a duty would result in a "flood of lawsuits." (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 944.) Although the court concluded that Gilead "overstate[d]" this concern (*ibid.*), it acknowledged that the duty could extend to "a potentially large class of persons" (*id.* at p. 945). The Court of Appeal nevertheless concluded — without further explanation — that "most plaintiffs would likely face a difficult road in establishing a breach of the duty of reasonable care." (*Id.* at p. 944.) It is far from clear, however, that manufacturers' decisions in this context would routinely be found to be reasonable and nonnegligent, given that such determinations hinge on inherently uncertain judgments, as described above, about when an alternative drug is sufficiently developed, whether later-stage clinical trials are likely to be

successful, how much delay in commercializing the alternative drug is tolerable, and how to prioritize competing therapies.

The dissent contends that this duty would impose little burden because manufacturers have "theoretically" always been subject to it. (Dis. opn. of Evans, J., *post*, at p. 28.) But that assertion conflates section 1714's general duty of care with the unprecedented theory of liability plaintiffs seek to impose here. Neither the dissent nor plaintiffs identify a single decision recognizing a duty requiring manufacturers to develop and commercialize without delay an alternative drug to replace a concededly nondefective one. This bears repeating: not once in the dissent's 29 pages does it cite a single case in this state or any other finding liability on such a theory. The closest it comes is our decision in *Mexicali Rose* — a case involving a restaurant's negligent failure to remove a harmful chicken bone from an enchilada. (Dis. opn. of Evans, J., *post,* at pp. 6–7.) But, for the reasons described above, this case bears little resemblance to plaintiffs' theory of liability. Moreover, it makes little sense to premise an entirely new form of liability in a dispute concerning complex life-saving drugs on a case involving a chicken bone in an enchilada.

The dissent's remaining out-of-state authorities likewise miss the mark. They involve traditional negligent design, manufacturing, marketing, or misrepresentation claims challenging allegedly dangerous products — claims our decision leaves untouched. (See dis. opn. of Evans, J., *post*, at pp. 29, 31; see also *State v. Purdue Pharma L.P.* (R.I., Aug. 16, 2019, No. PC-2018-4555) 2019 WL 3991963, p. *15 [recognizing duty " 'to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs' "]; *Ohio County Commission v. Express Scripts, Inc.* (N.D.W. Va., Dec. 23, 2024,

No. 5:24-CV-142) 2024 WL 5701504, p. *15 [alleging defendants collaborated with drug manufacturers to grossly misrepresent addictive qualities of opioids]; *Lance v. Wyeth* (2014) 624 Pa. 231, 277 [drug manufacturer marketed drug it allegedly knew was "too harmful to be used by anyone"].)

The dissent assumes that recognizing plaintiffs' proposed duty "would not disincentivize the development of drugs but merely allow for the possibility of liability when the development of less harmful alternatives is unreasonably delayed in order to maximize profit." (Dis. opn. of Evans, J., *post*, at p. 23.) In other words, the dissent appears to conclude that a holding from this court which, for the first time, subjects a drug manufacturer's research and development decisions regarding an alternative drug to potentially enormous tort liability would have little effect on manufacturers' willingness to pursue alternative forms of treatment. We disagree that manufacturers' incentives would be unaffected by the threat of such liability.

Moreover, we have said that "the most relevant burden is the cost to the defendants of upholding, not violating, the duty of ordinary care." (*Kesner*, *supra*, 1 Cal.5th at p. 1152.) The duty plaintiffs propose is particularly burdensome because it is not merely a duty to market an already developed and approved safer drug. Instead, it is a duty to continue researching and developing an alternative drug whenever preliminary data suggests it might ultimately prove safer than an existing one. According to the dissent, Gilead may be liable simply because it "paused development" after receiving supposedly "promising" results from a two-week clinical trial involving only 30 subjects. (Dis. opn. of Evans, J., *post*, at p. 9.) Under the threat of such liability, manufacturers will be compelled to invest substantial

sums and devote significant resources to developing backup or alternative drugs whenever preliminary research suggests a potential reduction in certain adverse side effects associated with an existing drug — or else risk a fact finder later concluding that their decision not to do so was unreasonable.

This would require manufacturers to undertake large-scale clinical testing. Plaintiffs' and the dissent's theory is that Gilead's 30-person Phase I/II study effectively *required* it to conduct a full-scale Phase III trial. Unlike phase I or phase II clinical trials, which typically involve fewer subjects studied over a more limited timeframe, phase III clinical trials are far more expansive. (See Step 3: Clinical Research, *supra*.) They often enroll thousands of participants, can take several years to complete, and may cost millions of dollars. (See *ibid*.; Moore et al., *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016* (Nov. 2018) 178 JAMA Internal Medicine 11 [finding median costs of phase III clinical trials for new therapeutic agents to be $19 million] <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2702287> [as of August 3, 2026].) Even if the results of phase III trials look promising, success is far from guaranteed: The FDA estimates only 25 to 30 percent of drugs tested in phase III trials will move on to the next development stage of seeking FDA approval. (Step 3: Clinical Research, *supra*.) And manufacturers must then incur additional costs to obtain FDA approval and bring the alternative drug to market. As a result, the duty would require manufacturers to invest years of time and large sums of money to develop drugs that may ultimately yield no benefit to anyone.

In this case, for example, Gilead estimated projected costs of approximately $100 million to conduct additional clinical

trials on TAF and complete the steps necessary to obtain FDA approval and bring the drug to market. Although the record does not show the actual costs Gilead incurred after resuming TAF development in 2010, it does indicate that commercialization took an additional five years. During that five-year period, Gilead conducted multiple phase III clinical trials involving TAF, the first of which lasted 48 weeks.

The dissent nevertheless suggests that these burdens are justified because a manufacturer's patent rights diminish the ordinary incentives to develop safer alternatives and that negligence liability is therefore needed as an additional safeguard. (Dis. opn. of Evans, J., *post*, at pp. 21–22.) In effect, the dissent proposes a new negligence rule applicable only to patent holders, under which patent protection itself justifies imposing tort liability for delaying the development and commercialization of alternative drugs. The dissent cites no authority recognizing such a rule, and we are aware of none. Congress has already determined that temporary patent exclusivity is warranted in light of the extraordinary time, expense, and risk associated with developing new medicines. Requiring manufacturers, under threat of tort liability, to accelerate the development and commercialization of products that may supplant their own patented drugs would substantially diminish the value of that legislatively created incentive and risk upsetting the careful balance Congress struck.

The burdens on manufacturers resulting from the duty are far greater than those we identified in *Verdugo v. Target Corp*. (2014) 59 Cal.4th 312, where we concluded that requiring Target to purchase, maintain, and train personnel in the use of automatic external defibrillators at its retail stores "would

impose considerably more than a minor or minimal burden on a business establishment." (*Id.* at p. 340.) They are also more substantial than those we described in *T.H. v. Novartis Pharmaceuticals Corp*. (2017) 4 Cal.5th 145, where we recognized that brand-name manufacturers have a duty to warn not only about the risks of their own drugs, but also about the risks associated with generic bioequivalents manufactured by other companies. (*Id.* at p. 156.) We reasoned that brand-name manufacturers already have a legal duty to update and maintain adequate warning labels on brand-name drugs for known or scientifically knowable side effects associated with those drugs, and federal law requires generic manufacturers to copy those labels. (*Id*. at p. 170.) Hence, "where the brand-name manufacturer provides an adequate label" for its own drug, "it necessarily has also fulfilled its duty with respect to the generic bioequivalent." (*Ibid*.)

By contrast, requiring drug manufacturers not to unreasonably delay bringing alternative drugs to market would impose substantial burdens. As detailed above, such a duty would likely compel manufacturers to devote significant time, money, and resources to developing and commercializing drugs they might not otherwise prioritize. We therefore conclude that this factor weighs in favor of recognizing an exception to any duty of care that might otherwise apply in this context. The dissent's reliance on *Novartis* is misplaced. (Dis. opn. by Evans, J., *post*, at p. 25.) The burden of requiring accurate warning labels for drugs that are *already on the market* is fundamentally different from imposing a legal obligation to continue investing

in and developing alternative drugs based solely on promising but preliminary clinical trials.

The final policy factor is the availability and cost of insurance. (*Rowland*, *supra*, 69 Cal.2d at p. 113.) In *Brown*, we found that public policy considerations weighed against imposing strict liability for design defects in prescription drugs, in part because the resulting increase in litigation would likely raise insurance costs — if insurance were available at all. (*Brown*, *supra*, 44 Cal.3d at pp. 1063–1065.) Although *Brown* involved a strict liability claim and, thus, a potentially greater volume of claims than the negligence theory asserted here, many of the concerns we identified in *Brown* apply here as well. As we explained in *Brown*, "[t]he possibility that the cost of insurance and of defending against lawsuits will diminish the availability and increase the price of pharmaceuticals is far from theoretical." (*Id.* at p. 1064.) Indeed, the added expense of insuring against liability for failure to commercialize a safer drug without delay "could place the cost of medication beyond the reach of those who need it most." (*Id.* at p. 1063.)

The Court of Appeal dismissed these concerns on the ground that the duty would not meaningfully expand drug manufacturers' exposure to liability because it applies only where (1) the manufacturer has already invented or developed an alternative drug and (2) knows that the alternative "will avoid significant side effects" associated with an existing drug. (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 944.) The court further emphasized that the duty requires only that manufacturers "act with reasonable care" in their development and commercialization decisions. (*Ibid.*) As already discussed, however, these purported limitations offer little practical constraint. Drug manufacturers routinely develop backup

candidates in parallel with lead candidates, and there is substantial uncertainty as to how to determine whether a particular backup candidate is sufficiently "invented" or "developed" to the point that the manufacturer must commercialize the drug without undue delay. In addition, a manufacturer cannot know — based on preliminary clinical data alone — the backup candidate is "safer" than the lead candidate. Moreover, assessing the "reasonableness" of a manufacturer's delay in developing or commercializing an alternative drug requires a retrospective evaluation of complex prioritization decisions made with only preliminary clinical data, such as whether to pursue alternatives that mitigate some patient risks while exacerbating others, or to allocate resources toward therapies for unmet medical needs rather than refining nondefective drugs already on the market. This inquiry poses a substantial risk of hindsight bias.

For these reasons, the duty would likely result in significantly greater liability exposure than the Court of Appeal perceived. The court's reliance on *Carlin*, *supra*, 13 Cal.4th 1104 does not alter this conclusion, because *Carlin* addressed a manufacturer's duty to warn of known or knowable risks associated with a drug that has already been placed on the market after completing all clinical trials and obtaining FDA approval. (See *id.* at p. 116.) By contrast, the duty asserted here would expose manufacturers to liability for research, development, and commercialization decisions made long before a drug is approved or marketed, and it would require a backward-looking analysis of scientific judgments and resource-allocation decisions based on incomplete and evolving data.

This factor accordingly weighs in favor of recognizing an exception to the default duty of care.

On balance, the *Rowland* factors support a judicial exception to the default duty in this context. Because a drug manufacturer cannot determine a drug's safety and efficacy during the early stages of clinical testing, it cannot reasonably foresee that any delay in developing and commercializing an alternative drug will harm users of an existing one. In addition, the connection between a manufacturer's decision to delay developing and commercializing an allegedly safer alternative drug and a plaintiff's injury from an existing one is attenuated. It depends on a chain of uncertain scientific outcomes and independent decisions by regulators, physicians, and patients.

Rowland's public policy factors also weigh against recognizing a duty: Moral blame is not meaningfully implicated, given the morally neutral and socially valuable reasons that may underlie drug development decisions and given the lack of reasonable, practicable ameliorative steps a drug manufacturer could take. In addition, while a duty might prevent some harms, it also risks distorting research priorities, discouraging innovation, and inviting hindsight-based second-guessing of complex scientific judgments. Finally, the burden such a duty would impose on drug manufacturers would be substantial. For these reasons, we conclude that a drug manufacturer has no duty of care when deciding whether and when to develop and commercialize an allegedly safer alternative drug.

The dissent observes that we have "never before held that drug manufacturers are entitled to an exception to the default negligence duty of care" under *Rowland*. (Dis. opn. of Evans, J., *post*, at p. 13.) That is unsurprising, given that we have never

before been presented with plaintiffs' novel theory that a drug manufacturer may be liable in negligence for allegedly delaying the development and commercialization of an alternative drug to replace a concededly nondefective one.

Ultimately, the dissent's application of the *Rowland* factors turns the analysis into a "heads I win, tails you lose" exercise, in which every factor necessarily disfavors recognizing an exception to any duty. As described above, the dissent asserts that the knowledge component of the foreseeability inquiry can only be resolved by a fact finder. (Dis. opn. of Evans, J., *post*, at p. 15.) But if that were so, this factor would almost never weigh in favor of an exception to a duty of care. The dissent similarly concludes that the alleged harm was foreseeable because Gilead's decision not to pursue an alternative drug was "the first step in plaintiffs' continued [harm]" and the "root cause of plaintiffs' alleged harm," but ignores all of the intervening decisions and conduct — such as clinical trial results, FDA approval, or prescribing decisions — that may determine whether such harm occurs at all. (*Id.* at p. 14.) The dissent's reasoning reduces the foreseeability inquiry to the allegation of negligence itself: the harm is foreseeable because the defendant acted negligently. We have never applied *Rowland*'s foreseeability factor so broadly.

The dissent's moral blame analysis suffers from the same flaw. Its focus on "the reaping of a profit and inherent power imbalance between plaintiffs and defendants" (dis. opn. of Evans, J., *post*, at p. 18) describes virtually every negligence action against a business. If a company's status as a for-profit enterprise necessarily establishes moral blame, that factor too

will almost always favor liability. The dissent turns application of the *Rowland* factors into a vain exercise.

In recognizing an exception to any duty of care a manufacturer may otherwise owe, we do not minimize the seriousness of the injuries plaintiffs allegedly suffered. Rather, our holding reflects the limits of common law negligence as a tool for regulating the research, development, and commercialization decisions regarding prescription drugs — an area already subject to extensive federal oversight. Negligence law is poorly suited to supervise forward-looking decisions grounded in uncertain, incomplete, and evolving clinical data through retrospective assessments of reasonableness.

The dissent repeatedly characterizes today's decision as granting pharmaceutical manufacturers "sweeping immunity." (Dis. opn. of Evans, J., *post*, at pp. 1, 29, 32.) It does not. The FDA rigorously evaluates new drugs before approving them for commercialization. In addition, plaintiffs injured by FDA-approved drugs may seek relief under traditional products-liability principles. Drug manufacturers remain subject to traditional tort and statutory claims arising from defective products or wrongful conduct. (*Brown*, *supra*, 44 Cal.3d at p. 1069 & fn. 12) [drug manufacturers are not strictly liable for design defects but remain liable for negligent design, manufacturing defects, and failure to warn of known or reasonably knowable risks].) For example, plaintiffs may try to establish that a manufacturer violated its duty to market a drug free from defects by showing that an existing drug was negligently designed, perhaps due to the availability of an alternative design whose benefits outweighed the burden of adopting it. Plaintiffs may also be able to pursue relief under applicable consumer protection laws, and in appropriate

circumstances under common-law fraud principles, by establishing that a drug manufacturer engaged in unlawful, unfair, or fraudulent conduct, including by withholding material information or misleading the public.

What today's decision declines to do is recognize, for the first time anywhere, sweeping *liability* for injuries caused by a concededly nondefective drug because the manufacturer allegedly failed to make a different drug available sooner. Imposing such liability would create substantial burdens and would risk adverse consequences for pharmaceutical innovation, public health, and patient safety. For these reasons, we conclude that drug manufacturers do not owe a duty of care to users of a nondefective drug when making decisions about whether and when to commercialize an allegedly safer alternative drug.

III. DISPOSITION

We reverse the judgment of the Court of Appeal and remand to that court with directions to issue a writ of mandate directing the trial court to vacate its order denying summary judgment and to enter a new order granting summary judgment for Gilead on all causes of action.

GROBAN, J.

We Concur:

CORRIGAN, J.
LIU, J.
KRUGER, J.
DESAUTELS, J.*

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* Associate Justice of the Court of Appeal, First Appellate District, Division Two, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.

GILEAD TENOFOVIR CASES

S283862

Concurring Opinion by Chief Justice Guerrero

It is black letter law that, in order to pursue a negligence claim against a manufacturer for damages based on the use of its product, "a plaintiff must prove that a defect caused injury." (*Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 479 (*Merrill*).) The majority recognizes this principle, and it expresses "significant doubts" that plaintiffs' theory of negligence *without* a product defect is viable. (Maj. opn., *ante*, at p. 13.) Nonetheless, the majority assumes that a manufacturer owes a duty of care to its customers and users beyond selling a nondefective product, and it concludes that an exception to that duty is warranted under the specific circumstances here. (*Id*. at pp. 13–14.)

While I understand the majority's inclination to avoid the fundamental questions raised by plaintiffs' novel theory, I believe such avoidance is unwarranted. A straightforward application of this court's precedents forecloses plaintiffs' theory of liability without defect. Fifty years ago, we held that an essential element of a negligence cause of action against a manufacturer was that the plaintiff "was injured by a defect in the product." (*Jiminez v. Sears, Roebuck & Co.* (1971) 4 Cal.3d 379, 383 (*Jiminez*).) We have never deviated from that requirement. (*Merrill*, *supra*, 26 Cal.4th at p. 479.) Plaintiffs' failure to allege an injury based on a product defect is therefore fatal to their claim. We need not make any assumptions regarding a broader duty or consider whether any exception

might be justified under the factors in *Rowland v. Christian* (1968) 69 Cal.2d 108, 113 (*Rowland*).

Plaintiffs contend that Civil Code section 1714 authorizes a negligence cause of action without proof of a defective product.[1] Plaintiffs are incorrect. Their contention interprets section 1714 in a vacuum, and it ignores the entire history of negligence law in California. Section 1714 was enacted in 1872, and it has never been interpreted to impose a broad duty of care on manufacturers. It generally reflects the common law, which for many decades sharply restricted negligence actions against manufacturers. The law of products liability freed plaintiffs from these traditional restrictions, but it did not simply allow any cause of action sounding in negligence. It required — and still requires — plaintiffs to prove certain elements in order to recover. Plaintiffs' rejection of products liability law does not allow them to avoid these elements. Instead, it leaves them with no cause of action at all.

In this case, plaintiffs' failure to allege a product defect means they have abandoned any claim that tenofovir disoproxil fumarate (TDF) is unsafe. In other words, plaintiffs cannot argue that the likelihood and gravity of any harmful side effects justifies the burden on defendant Gilead Sciences, Inc. (Gilead) to commercialize an alternative drug like tenofovir alafenamide fumarate (TAF). (See *Jiminez*, *supra*, 4 Cal.3d at p. 384.) Gilead acted responsibly by releasing TDF to the market and saving countless lives. But plaintiffs would have Gilead go further. They would require Gilead, anytime it releases a safe and nondefective drug like TDF, to take every reasonable step

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[1] Subsequent statutory references are to the Civil Code.

to develop and market *additional* drugs for the *same* condition, or face tort liability for its failure to do so. This unjustified and dramatic expansion of a manufacturer's duty to its customers and users ignores nearly a century of precedent by this court.

While the majority appears sympathetic to this analysis, it stops short of adopting it as the basis for its holding. Instead, the majority assumes plaintiffs are correct that manufacturers owe their customers a broad duty of care, and it holds only that the specific circumstances here justify an exception to this broad duty. Although I agree such an exception would be justified, if manufacturers did have a broad duty of care, I do not support the majority's approach. It calls into question fundamental principles of products liability law, and it creates unnecessary uncertainty regarding the scope of a manufacturer's duty in other industries and in other circumstances. I therefore concur only in the result reached by the majority, but not its reasoning.

I. SECTION 1714 AND MANUFACTURER LIABILITY

Enacted in 1872, section 1714 provides in relevant part, "Everyone is responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter has, willfully or by want of ordinary care, brought the injury upon himself or herself." (§ 1714, subd. (a).)

Notwithstanding this broad language, manufacturers historically had no duty in tort to consumers with whom they had no contractual relationship. Consumers injured by the use of a product had little recourse against the product's manufacturer, unless the consumer dealt with the manufacturer directly. (See 1 Owen & Davis on Products

Liability (4th ed. 2026) § 1:10 (Owen & Davis).) The common law "prohibited negligence actions against 'remote' manufacturers, parties with whom injured plaintiffs had no 'privity of contract.' " (*Ibid.*; see, e.g., *Lewis v. Terry* (1896) 111 Cal. 39, 44.) As this court has recognized, "the common law, as a general rule, throws a strong arm of protection around the manufacturer, warding off claims of third persons, not direct purchasers, for personal injuries sustained from use of articles so manufactured and sold by him." (*Kalash v. Los Angeles Ladder Co.* (1934) 1 Cal.2d 229, 231 (*Kalash*); see *Beacon Residential Community Assn. v. Skidmore, Owings & Merrill LLP* (2014) 59 Cal.4th 568, 574.)

Section 1714 did not itself prompt reconsideration of these principles. It largely reflected the common law; it did not subvert it. In one early case, we said, "The common law of England is declared to be the rule of decision in all the courts of this state so far as not repugnant to or inconsistent with our constitution and statutes. [Citation.] The Civil Code was not designed to embody the whole law of private and civil relations, rights and duties; it is incomplete and partial; and except in those instances where its language clearly and unequivocally discloses an intention to depart from, alter, or abrogate the common-law rule concerning a particular subject matter, a section of the code purporting to embody such doctrine or rule will be construed in the light of common-law decisions on the same subject." (*In re Estate of Elizalde* (1920) 182 Cal. 427, 433; see *Li v. Yellow Cab Co.* (1975) 13 Cal.3d 804, 815 (*Li*).)

Nonetheless, the common law principles governing manufacturer liability were the subject of further development in the courts. "By 1900, dissatisfaction with the privity bar had generated certain exceptions," including where a plaintiff

established " 'an act of negligence of a manufacturer or vendor which is imminently dangerous to the life or health of mankind [in preparing] an article intended to preserve, destroy, or affect human life.' " (Owen & Davis, *supra*, § 1:10.)

In *Kalash*, this court adopted the broad exception articulated in the seminal case of *MacPherson v. Buick Motor Co.* (N.Y. 1916) 111 N.E. 1050, 1053 (*MacPherson*): " '[The exception] is not limited to poisons, explosives, and things of like nature, to things which in their normal operation are implements of destruction. If the nature of a thing is such that it is reasonably certain to place life and limb in peril when negligently made, it is then a thing of danger. Its nature gives warning of the consequences to be expected. If to the element of danger there is added knowledge that the thing will be used by persons other than the purchaser, and used without new tests, then irrespective of contract, the manufacturer of this thing of danger is under a duty to make it carefully.' " (*Kalash*, *supra*, 1 Cal.2d at pp. 231–232.)

This duty did not arise from a contractual relationship. It was implied by law. As *Kalash* recognized, " 'We have put aside the notion that the duty to safeguard life and limb, when the consequences of negligence may be foreseen, grows out of contract and nothing else. We have put the source of the obligation where it ought to be. We have put its source in the law.' " (*Kalash*, *supra*, 1 Cal.2d at p. 232, quoting *MacPherson*, *supra*, 111 N.E. at p. 1053.) Although the precise source of the duty was variously identified, we have held the "true reason for the rule" is found in the Civil Code, including section 1714. (*Dahms v. General Elevator Co.* (1932) 214 Cal. 733, 739 (*Dahms*).)

Thus, from its origins, the law of products liability arose not in opposition to section 1714, but as an interpretation of its broad foundational principle, as "developed . . . from the common law." (*Kentucky Fried Chicken of Cal., Inc. v. Superior Court* (1997) 14 Cal.4th 814, 828 (*Kentucky Fried Chicken*).)

Further development resulted in the modern law of products liability. The exception for a product " 'negligently made' " (*Kalash*, *supra*, 1 Cal.2d at p. 231) was split into two analytically distinct concepts: negligent manufacturing and negligent design. (*Merrill*, *supra*, 26 Cal.4th at p. 479; see Rest.2d Torts, §§ 395 [negligent manufacturing], 398 [negligent design].) Additionally, courts recognized that a manufacturer may be liable for injuries caused by its negligent failure to warn of known or reasonably knowable dangers in its products. (*Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 64 (*Stevens*); see *Webb v. Special Electric Co., Inc.* (2016) 63 Cal.4th 167, 181 (*Webb*); Rest.2d Torts, § 388.)

Thus, almost 40 years after *Kalash*, this court observed, "[O]ver the years a considerable body of law has been developed as to negligence permitting definitive instructions based upon tested and settled principles." (*Jiminez*, *supra*, 4 Cal.3d at p. 384.) For example, we stated in *Pike v. Frank G. Hough Co.* (1970) 2 Cal.3d 465 that the relevant principle of negligent design was settled: "The duty of a manufacturer with respect to the design of products placed on the market is defined in the Restatement Second of Torts, section 398: 'A manufacturer of a chattel made under a plan or design which makes it dangerous for the uses for which it is manufactured is subject to liability to others whom he should expect to use the chattel or to be endangered by its probable use for physical harm caused by his failure to exercise reasonable care in the adoption of a safe plan

or design.' Thus, the manufacturer must use reasonable care 'to so design his product as to make it not accident-proof, but safe for the use for which it was [*sic*] intended.' [Citation.] What is 'reasonable care,' of course, varies with the facts of each case, but it involves a balancing of the likelihood of harm to be expected from a machine with a given design and the gravity of harm if it happens against the burden of the precaution which would be effective to avoid the harm." (*Id.* at p. 470; accord, *Jiminez*, at p. 384.)

To shorthand these principles, courts have often described a negligently designed or negligently manufactured product, or a product accompanied by inadequate warnings, as "defective" or suffering from a specific "defect." (*Merrill*, *supra*, 26 Cal.4th at pp. 479–480; see, e.g., *Webb*, *supra*, 63 Cal.4th at p. 181; *Jiminez*, *supra*, 4 Cal.3d at p. 383; *Kalash*, *supra*, 1 Cal.2d at p. 231; *Dahms*, *supra*, 214 Cal. at pp. 738, 742; *MacPherson*, *supra*, 111 N.E. at pp. 1051, 1053.) The law of products liability, then, has been described as " 'the area of the law involving the liability of those who supply goods or products for the use of others to purchasers, users, and bystanders for losses of various kinds resulting from so-called defects in those products.' " (*Merrill*, at p. 478.)

The defect requirement is crucial. "[D]efect is the conceptual linchpin that holds products liability law together; a system of liability without defect is beyond the capacity of courts to implement." (Henderson & Twerski, *Closing the American Products Liability Frontier: The Rejection of Liability Without Defect* (1991) 66 N.Y.U. L.Rev. 1263, 1267.)

II. SECTION 1714 AS A SEPARATE DUTY

Plaintiffs argue they can pursue a negligence action for injuries caused by TDF without alleging a product defect, based on the broad language of section 1714. They point out that we have described section 1714 as articulating the "general rule in California . . . that '[e]veryone is responsible . . . for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person . . . .'" (*Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 771 (*Cabral*).)

The flaw in plaintiffs' argument is that the general duty in section 1714 has never been held sufficient to impose liability on a manufacturer for injuries caused by the use of a manufacturer's product. Instead, courts developed the law of products liability to hold manufacturers liable, but only where plaintiffs can allege a defect caused their injuries. If section 1714 itself authorized a plaintiff to sue in negligence without proof of a defect, it would have been unnecessary for courts to develop the principles of products liability described above, and it would be unnecessary for plaintiffs to adhere to them. In other words, plaintiffs ask this court to simply recognize that section 1714 has always authorized a negligence claim against a manufacturer for damages caused by the use of its product, even in the absence of a defect, and "to brush aside all of the misguided decisions which have concluded otherwise up to the present day." (*Li*, *supra*, 13 Cal.3d at p. 817.) This "arresting contention" refutes itself. (*Ibid.*)

As noted, section 1714 "states a civil law principle that is the foundation of our negligence law." (*Kentucky Fried Chicken*, *supra*, 14 Cal.4th at p. 828.) But it is merely the foundation. It

does not supplant the more specific standards that "may be established by judicial decision, statute or ordinance." (*Id*. at p. 824.) " '[T]he proper conduct of a reasonable person under particular situations may become settled by judicial decision or be prescribed by statute or ordinance,' " and in that situation the general duty of care no longer applies. (*Ramirez v. Plough, Inc.* (1993) 6 Cal.4th 539, 547; see Rest.2d Torts, § 285.) Here, our prior precedents have defined the scope of a manufacturer's duty of care to avoid harm caused by the use of its products. Plaintiffs cannot rely on section 1714 to circumvent those precedents.[2]

We confronted a similar situation in *Parsons v. Crown Disposal Co.* (1997) 15 Cal.4th 456, 460 (*Parsons*), where a plaintiff brought a general negligence claim against a defendant based on injuries sustained when his horse was startled by defendant's trash collection activities. We observed that "the

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[2] In numerous other contexts, we have recognized that section 1714's broad statement of duty cannot simply be applied to every plaintiff and defendant. "A case in point is liability in negligence for purely economic losses, which is 'the exception, not the rule' under our precedents. [Citation.] And that holds true even though . . . section 1714 does not, by its terms, 'distinguish among injuries to one's person, one's property or one's financial interests.' " (*Southern California Gas Leak Cases* (2019) 7 Cal.5th 391, 400; see *Bily v. Arthur Young & Co.* (1992) 3 Cal.4th 370, 397.) Other examples include the duty owed to coparticipants in active sports, which is limited to intentional injuries to another participant or "conduct that is so reckless as to be totally outside the range of the ordinary activity involved in the sport" (*Knight v. Jewett* (1992) 3 Cal.4th 296, 320) and the duty to warn third parties of danger, which is limited to circumstances where the plaintiff can establish a special relationship between the defendant and the plaintiff or the defendant and the third party (*Tarasoff v. Regents of University of California* (1976) 17 Cal.3d 425, 435–436).

nature and scope of defendant's duty in these circumstances is established by the considerable line of authority addressing the question of a defendant's potential liability for injuries resulting from the frightening of a horse." (*Id.* at p. 462.) At common law, "courts developed a remarkably uniform rule, holding that a plaintiff whose horse 'shied' or 'spooked' and caused damage because of the noise, sight, or odor caused by the defendant's *regular and necessary conduct*, cannot state a cause of action for negligence, because the defendant in such a case has breached no duty of care." (*Id.* at p. 466.) "In each category of case, however, the courts recognized 'exceptions' to the general rule of nonliability." (*Id.* at p. 469.) These exceptions allowed liability where the plaintiff could establish, for example, that a defendant operated a machine "in a careless or imprudent manner, or causes noises or emissions unnecessary to the regular operation of the machine." (*Id.* at pp. 469–470.)[3]

In *Parsons*, we recognized the general duty of reasonable care embodied by section 1714. (*Parsons*, *supra*, 15 Cal.4th at p. 472.) But we did not apply section 1714 in a vacuum. We examined "the existence and scope of duty" "[w]ith these principles and this history in mind." (*Parsons*, at pp. 473, 472.) In the end, we saw "no basis for treating defendant's garbage collection truck differently from the various machines and

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[3] Courts recognized other exceptions where "the defendant fails to take reasonable protective actions after it knows that the plaintiff's horse actually has become frightened," "the defendant or its employees conduct its machinery in an unnecessary or malicious fashion designed to cause fright," or "the defendant violates a safety statute designed to protect the class of which the plaintiff is a member." (*Parsons*, *supra*, 15 Cal.4th at p. 470.)

devices discussed [in prior cases], or for increasing the burden on machine operators over what was considered reasonable in an earlier age." (*Id.* at p. 474.) We "reject[ed] plaintiff's assertion that defendant owed an expansive duty to guard against frightening horses" but "affirm[ed] that defendant was obligated to conduct itself in accordance with the limited common law duty" established previously. (*Id.* at p. 477.)

A similar approach governs this case. Plaintiffs cannot simply invoke section 1714 to avoid the common law principles governing their cause of action against Gilead. (See *Parsons*, *supra*, 15 Cal.4th at p. 461 [criticizing the lower court for adopting "a broad, expansive duty . . . that takes no account of the established authority" defining the defendant's duty of care].) Instead, plaintiffs must justify a departure from common law principles based on "'"'the sum total of those *considerations of policy* which lead the law to say that the particular plaintiff is entitled to protection.'"'" (*Id.* at p. 472.) "Duty is not universal; not every defendant owes every plaintiff a duty of care. A duty exists only if ' "the plaintiff's interests are entitled to legal protection against the defendant's conduct." ' " (*Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 213.)

Plaintiffs do not attempt to justify a departure from traditional principles of products liability. Instead, they claim that section 1714 itself accomplishes this result. They are mistaken, for reasons I have already explained.

Plaintiffs argue that *Rowland*, *supra*, 69 Cal.2d 108, supports their view of section 1714. In *Rowland*, this court abandoned the common law approach to a landowner's duties, which was based on the status of the injured plaintiff as a licensee, an invitee, or a trespasser. (*Rowland*, at pp. 113–114.)

By the time *Rowland* was decided, the common law approach had become riddled with complex and confusing exceptions. (*Id.* at pp. 115–116.) We remarked, "Whatever may have been the historical justifications for the common law distinctions, it is clear that those distinctions are not justified in the light of our modern society and that the complexity and confusion which has arisen is not due to difficulty in applying the original common law rules — they are all too easy to apply in their original formulation — but is due to the attempts to apply just rules in our modern society within the ancient terminology." (*Id.* at p. 117.) We concluded that adhering to these common law distinctions "can only lead to injustice or, if we are to avoid injustice, further fictions with the resulting complexity and confusion." (*Id.* at p. 119.)

Thus, even in *Rowland*, we did not treat section 1714 as solely determinative of a defendant's duty. We examined the traditional common law approach to determine whether it continued to be persuasive in light of the "basic policy" of the state embodied in section 1714. (*Rowland*, *supra*, 69 Cal.2d at p. 118.) "The factors which may in particular cases warrant departure from this fundamental principle do not warrant the wholesale immunities resulting from the common law classifications . . . ." (*Id.* at p. 119.) We did not read section 1714 in a vacuum, and we did not hold that section 1714 itself allowed any plaintiff to sue any defendant for negligence, regardless of any common law limitation on a defendant's duty under specific circumstances.[4]

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[4] In addition, at issue in *Rowland* were "ancient concepts as to the liability of the occupier of land" (*Rowland*, *supra*,

Plaintiffs further argue that, even in the realm of products liability law, proof of a product defect is not always required to support a negligence action against a manufacturer. This argument is refuted by the history of products liability law discussed above. Moreover, the cases cited by plaintiffs do not support dispensing with the defect requirement.

For example, in *Stevens*, *supra*, 9 Cal.3d 51, we concluded that plaintiffs had presented sufficient evidence to sustain a claim against a drug manufacturer for negligent failure to warn. (*Id*. at p. 64.) The defect in that case was the incorrect or inadequate information provided to medical professionals about the product. (*Id*. at pp. 64–65.) Evidence of the manufacturer's overpromotion, along with its inadequate product warnings, established a breach of the manufacturer's specific duty in products liability " 'to exercise reasonable care to inform [users or their physicians] of [a product's] dangerous condition or of the facts which make it likely to be dangerous.' " (*Id*. at p. 64; see *id*. at pp. 66–67.) We did not suggest that proof of a product defect was unnecessary. To the contrary, we have confirmed that liability for a manufacturer's negligent failure to warn

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69 Cal.2d at p. 119) that were no longer "justified in the light of our modern society" (*id*. at p. 117). The law of products liability, by contrast, arose in response to the commercial realities of modern society. (See Owen & Davis, *supra*, § 1:10 [discussing legal developments after "manufacturing and retailing functions separated in the 1800s during the course of industrialization"].) Similarly, the "ancient concepts" abandoned in *Rowland* stood in opposition to the general principle in section 1714. (*Rowland*, at p. 119.) The law of products liability, by contrast, explicitly furthers its purpose. (*Dahms*, *supra*, 214 Cal. at p. 740.)

depends on proof of a " ' "warning defect." ' " (*Webb*, *supra*, 63 Cal.4th at p. 181.)

Similarly, in *Hasson v. Ford Motor Co.* (1977) 19 Cal.3d 530, 543–544, we upheld a jury verdict against a manufacturer based on negligent failure to warn. In response to a special interrogatory, the jury had found "that there had been no 'defect' in the [plaintiffs'] vehicle 'at the time it was manufactured and sold.' " (*Id.* at p. 539.) The manufacturer argued that this finding was fatally inconsistent with the jury's finding of negligence. (*Id.* at p. 540.) We disagreed, but not because proof of a defective product was unnecessary. Instead, we held, "The jury could reasonably believe that the interrogatory . . . intended to *exclude* consideration of any 'defect' based on a failure to warn." (*Id.* at p. 543.)

Plaintiffs rely heavily on *Mexicali Rose v. Superior Court* (1992) 1 Cal.4th 617, but it has no application here. There, we approved of a specific duty of care, i.e., a restaurant must "exercise reasonable care in the preparation of [its] food." (*Id.* at p. 633.) We recognized that a restaurant patron injured by the presence of a natural substance in food (there, a chicken bone) may maintain an action based on negligent preparation even though the food is not considered defective. (*Ibid.*) But our recognition stemmed from the unique context of food, which may have qualities or components that are both (1) natural and inherent in the food itself and (2) potentially harmful when included in a restaurant dish. It would not make sense to call such a natural quality or component a "defect" in the food. Contrary to the view of the Court of Appeal below, *Mexicali Rose* does not stand for the proposition that "a plaintiff may recover under the doctrine of negligence for harm caused by a product otherwise subject to the doctrine of strict liability,

notwithstanding the plaintiff's inability to prove a product defect." (*Gilead Tenofovir Cases* (2024) 98 Cal.App.5th 911, 926.) A food product that contains only natural substances is not subject to the doctrine of strict liability because "the food cannot be determined unfit or defective." (*Mexicali Rose*, at p. 633.) In any event, our endorsement of a specific cause of action against restaurants based on their negligence resulting in nondefective (but still harmful) food does not say anything about the defect requirement in the context of nonfood products.

Finally, plaintiffs contend that the defect requirement improperly imports an element from the doctrine of strict liability into a negligence cause of action. Again, plaintiffs are incorrect. As discussed, "under either a negligence or a strict liability theory of products liability, to recover from a manufacturer, a plaintiff must prove that a defect caused injury." (*Merrill*, *supra*, 26 Cal.4th at p. 479.) In negligence actions, we have consistently identified a product defect as a required element, even before the emergence of the doctrine of strict products liability. (See, e.g., *Kalash*, *supra*, 1 Cal.2d at p. 231; *Dahms*, *supra*, 214 Cal. at pp. 738, 742; see also *MacPherson*, *supra*, 111 N.E. at pp. 1051, 1053.) Plaintiffs further contend that these early cases refer to product defects only because plaintiffs alleged a defect, not because a product defect was required. They maintain that, at common law, remote manufacturers could be held liable in general negligence for injuries caused by a product, without proof of a product defect. Plaintiffs cite no authority for this contention, and it flies in the face of a century of precedent establishing that remote manufacturers were *not* liable *except* where plaintiffs could prove a product was defective.

In sum, neither section 1714 nor our precedents provide any basis for plaintiffs' theory of negligence without proof of defect. In order to maintain a negligence action against a manufacturer based on injuries caused by the manufacturer's product, a plaintiff must prove the injuries were caused by a defective product. A plaintiff may not avoid this essential element by invoking section 1714.

III. THE MERITS OF A SEPARATE DUTY

Because they contend that section 1714 already imposes a broad duty of reasonable care on manufacturers, plaintiffs do not attempt to justify its creation. Nonetheless, it is easy to see why expanding a manufacturer's tort liability to encompass every step leading to a manufacturer's decision *not* to develop an alternative product would be unwarranted.

Existing law already requires manufacturers to consider reasonable alternatives to their products. For example, to avoid liability for a negligent design defect, a manufacturer must act reasonably in balancing the likelihood and gravity of the harm to be expected from the existing design against the burden of adopting an alternative design that would avoid the harm. (*Merrill*, *supra*, 26 Cal.4th at p. 479.) Indeed, the manufacturer would also be strictly liable " 'either (1) if the product has failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or (2) if . . . the benefits of the challenged design do not outweigh the risk of danger inherent in such design.' " (*Ibid.*) As to the latter, if a plaintiff can show that the design of a product caused injury, the plaintiff is entitled to relief unless the manufacturer can " 'establish, in light of the relevant factors, that, on balance, the benefits of the challenged design outweigh the risk of danger

inherent in such design.' " (*Kim v. Toyota Motor Corp.* (2018) 6 Cal.5th 21, 30.) Relevant considerations include " 'the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design.' " (*Ibid.*) Thus, under existing law, a manufacturer may be liable " ' "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor." ' " (*Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110, 142; see Rest.3d Torts, Products Liability, § 2(b).)

These principles ensure that manufacturers' products are reasonably safe and nondefective. But plaintiffs' broad duty of care would require manufacturers to go further. Every manufacturer could face liability for its failure to develop alternative products, or do so promptly, even where existing principles of products liability would not require the adoption of an alternative design at all, because the likelihood and gravity of any potential injuries would not justify the burden on a manufacturer to adopt an alternative design that would avoid the harm. (See *Jiminez*, *supra*, 4 Cal.3d at p. 384.) A manufacturer's liability would no longer turn on the safety of the products being sold, but instead on each business decision made in the course of *alternative* product development. Such a dramatic expansion of tort liability would be unprecedented and unjustified.

As a doctrinal matter, we examine certain considerations "to determine the existence and scope of duty," including " 'the foreseeability of harm to the plaintiff, the degree of certainty

that the plaintiff suffered injury, the closeness of the connection between the defendant's conduct and the injury suffered, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost, and prevalence of insurance for the risk involved.' " (*Parsons*, *supra*, 15 Cal.4th at p. 473.) Although these factors mirror the *Rowland* factors considered by the majority, they serve a different purpose in this context. The majority considers these factors to determine whether to recognize an *exception* to its assumed duty of care. (Maj. opn., *ante*, at p. 22.) But because our precedents already define a manufacturer's duty of care in this circumstance, an exception is not at issue. Instead, we must consider these factors to determine whether our precedents should be reconsidered and a manufacturer's duty *expanded* to encompass the broad duty plaintiffs seek to invoke. (See *Parsons*, at pp. 472–475.) Because plaintiffs contend section 1714 imposes a broad duty on all manufacturers, and it is not limited to the pharmaceutical industry, I consider these factors at a high level of generality.[5]

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[5] In their briefing, plaintiffs emphasize their specific allegations against Gilead, including that Gilead knew TAF was safer than TDF and that Gilead intentionally delayed its development of TAF in order to maximize its profits. These evidentiary allegations are relevant to show breach of a duty, but they do not aid a court in determining whether a duty exists in the first place. We found analogous details relating to the circumstances of an automobile accident irrelevant in *Cabral*, *supra*, 51 Cal.4th at page 774. We explained, "On the duty question that is presented here, the factual details of the accident are not of central importance. That [the driver] parked

To begin, the harm to plaintiffs in this context is not foreseeable. " '[A] court's task — in determining "duty" — is not to decide whether a particular plaintiff's injury was reasonably foreseeable in light of a particular defendant's conduct, but rather to evaluate more generally whether the category of negligent conduct at issue is sufficiently likely to result in the kind of harm experienced that liability may appropriately be imposed . . . .' " (*Parsons*, *supra*, 15 Cal.4th at p. 476.) It is not a factual assessment of foreseeability; it is a "very different and normative inquiry." (*Ibid.*)

The conduct at issue here is a manufacturer's decision not to release an alternative product. Innumerable steps might lead to such a decision, just as innumerable alternatives might exist to a product actually sold. As a categorical matter, any given decision *not* to release an alternative product, where the existing product is reasonably safe and nondefective, does not itself carry a sufficient risk of foreseeable harm. The negligent failure to release an alternative product is not inherently harmful. It constitutes no affirmative action. Indeed, it is only those rare alternative products that would avoid harm, yet not rise to the level of a reasonable alternative design under products liability

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16 feet from the outermost traffic lane, rather than six feet or 26 feet; that parking for emergencies was permitted in the dirt area he chose; that [the plaintiff] likely left the highway because he fell asleep or because of some unknown adverse health event, rather than from distraction or even intoxication — none of these are critical to whether [the driver] owed [the plaintiff] a duty of ordinary care. These facts may have been important to the jury's determinations of negligence, causation and comparative fault, but on duty California law looks to the entire 'category of negligent conduct,' not to particular parties in a narrowly defined set of circumstances." (*Ibid.*, italics omitted.)

law, that would be encompassed within plaintiffs' broad duty of care. In many industries, a manufacturer will have difficulty understanding the comparative impacts on safety of its existing products and yet-to-be released alternative products, including whether an alternative product would be safer along certain dimensions but less safe along others. This difficulty increases greatly if a manufacturer must foresee how each specific development decision will affect the ultimate product's safety. Even in industries where the level of scientific inquiry and knowledge is fairly high, it would still be difficult for manufacturers to gain sufficient knowledge to accurately foresee the risk of harm. (See maj. opn., *ante*, at pp. 24–26.)

Similarly, while in this context we can be relatively certain that a plaintiff suffered harm, the connection between defendant's conduct and the harm is quite attenuated. "[W]here the injury suffered is connected only distantly and indirectly to the defendant's negligent act, the risk of that type of injury from the category of negligent conduct at issue is likely to be deemed unforeseeable." (*Cabral*, *supra*, 51 Cal.4th at p. 779.) For example, where a nondefective product causes injury to a plaintiff, it is far from clear whether the harm would have been avoided by the release of an alternative product. The availability of consumer products depends on complicated distribution networks, and retail outlets may not even stock an alternative product. Even if available, the decision by a consumer to use a product may rest on any number of factors, and it may be pure chance whether a user chooses to use the original product, an alternative product, or some other manufacturer's product. Given this unpredictable and contingent path, the harm that a user might suffer from the use of a nondefective product is quite remote from a manufacturer's

decision to commercialize an alternative product. (See *Vasilenko v. Grace Family Church* (2017) 3 Cal.5th 1077, 1086 [harm is remote where it results from "the confluence" of decisions by various actors].)

Moreover, even if the risk of harm were sufficiently foreseeable, " 'we will not treat the mere presence' of such a finding, 'standing alone,' as imposing on defendant a duty to guard against injuries to plaintiff. [Citation.] As we have observed, 'social policy must at some point intervene to delimit liability' even for foreseeable injury [citation], and 'policy considerations may dictate a cause of action should not be sanctioned *no matter how foreseeable the risk*.' " (*Parsons*, *supra*, 15 Cal.4th at p. 476.) These policy considerations include the moral blame attached to the category of negligent conduct, the societal consequences of imposing a duty of care in this context, and the cost and availability of insurance for the risk involved.

The moral blame that attaches to a manufacturer's negligent decision to forgo release of an alternative product, when the product actually released is reasonably safe and nondefective, is fairly low. While ideally every product would be as safe as possible, and even safer alternatives would be freely available, a mistake that makes a manufacturer's portfolio of products somewhat less safe — but still safe and nondefective — is not highly morally blameworthy, when compared with other categories of negligent conduct.

While "the 'policy of preventing future harm is ordinarily served, in tort law, by imposing the costs of negligent conduct upon those responsible,' " we must consider in this context "both the positive and the negative societal consequences of

recognizing a tort duty." (*Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1026 (*Kuciemba*).) Here, the negative consequences of plaintiffs' broad duty would be significant. Given the difficulty of understanding the comparative risks and benefits of the original product and any unreleased alternative product, a prudent manufacturer would be incentivized to release many more products than necessary, dramatically increasing the costs ultimately borne by consumers. Alternatively, a prudent manufacturer would be incentivized to release fewer new products that benefit new classes of consumers or users, since each released product — even if reasonably safe and nondefective — risks exposing the manufacturer to liability for its failure to release alternative products. Overall, manufacturers would spend significantly more time and effort releasing alternative products rather than developing new innovations. (See maj. opn., *ante*, at pp. 37–50.)

Further, plaintiffs' broad duty would increase compliance and litigation costs, since every development decision could lead to tort liability. Since manufacturers might be exposed to liability for products they did not release, every possible alternative product (i.e., every development path not taken) would have to be scrutinized in the same manner as a product actually released. Moreover, by imposing liability on manufacturers who released only safe and nondefective products, plaintiffs' broad duty would threaten to impose liability " 'out of proportion to fault,' " contrary to the goal of California's tort law. (*Kuciemba*, *supra*, 14 Cal.5th at p. 1030.) It is fundamental that a manufacturer "should not be responsible for all injuries involving the use of its products." (*Cronin v. J.B.E. Olson Corp.* (1972) 8 Cal.3d 121, 133.) A manufacturer should be liable only "for all injuries proximately

caused by any of its products which are adjudged 'defective.' " (*Id*. at pp. 133–134.)

Similarly, insuring against the liability imposed by plaintiffs' alleged duty would be uncertain and costly. It will be difficult for insurers to predict a manufacturer's exposure to liability based on products the manufacturer has not developed or released. Insurers will therefore increase their premiums to cover the risk involved, if insurance for such unknown risks is even available.

In sum, plaintiffs have not shown that manufacturers' existing duties under the law of products liability should be expanded to encompass a broad duty of reasonable care with respect to all development decisions. (See *Parsons*, *supra*, 15 Cal.4th at p. 478.) A manufacturer that sells a reasonably safe and nondefective product does not owe its existing customers and users a duty to develop a reasonable alternative product.

IV. CONCLUSION

Because plaintiffs' general negligence cause of action rests on a flawed premise, and they have not attempted to satisfy the essential elements of a negligence claim under established products liability law, Gilead was entitled to summary judgment. Because the majority reaches the same result, but by different reasoning, I concur in the result only.

GUERRERO, C. J.

GILEAD TENOFOVIR CASES

S283862

Concurring Opinion by Justice Kruger

As the majority opinion explains, established precedent limits a manufacturer's liability in negligence for consumer injuries to cases in which plaintiffs prove a product defect. This precedent forecloses plaintiffs' theory of negligence, under which a manufacturer can be liable for selling a sufficiently safe, and thus defect-free, product if a jury later determines that the manufacturer should have spent its time and resources developing an even safer alternative product.

While I share the Chief Justice's skepticism that Civil Code section 1714 overrides this defect requirement, I am nonetheless willing to assume with the majority that there might be some conceivable theory of negligence, not yet identified in our cases, based on the sale of a nondefective product. Even assuming that manufacturers owe consumers a general duty of care apart from the marketing of defect-free products, I agree with the majority that foreseeability and public policy considerations would warrant an exception in this context. I write separately to underscore that the majority makes the threshold assumption for the sake of argument only. Together, the majority opinion and Chief Justice Guerrero's concurrence illustrate not only the tension between plaintiffs' proposed duty of care and established case law but also the significant administrability and public policy concerns that, as the majority says, "may ultimately undermine, rather than advance, public health and safety." (Maj. opn., *ante*, at p. 4.)

With these observations, I concur in the majority opinion.

KRUGER, J.

We Concur:

CORRIGAN, J.
DESAUTELS, J. *

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* Associate Justice of the Court of Appeal, First Appellate District, Division Two, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.

GILEAD TENOFOVIR CASES

S283862

Dissenting Opinion by Justice Evans

Today, the majority provides pharmaceutical manufacturers with sweeping immunity from negligence liability, no matter how unreasonably they may act or how much serious and avoidable harm they may cause consumers by intentionally delaying the commercialization of safer drugs. Pharmaceutical manufacturers benefit society by producing life-saving drugs. In exchange, they receive special accommodations, including exclusive patent protections and exemptions from strict products liability. Consequently, they reap substantial profits while serving an important public function. Given these existing protections, I do not believe drug manufacturers are further entitled to an exception to Civil Code section 1714's[1] default requirement that everyone must exercise ordinary care. Like other entities, drug manufacturers should be held liable for injuries caused when they act negligently or engage in willful misconduct.

The default duty of care should attach when drug manufacturers make decisions about whether and when to commercialize a drug known to be significantly safer than and as effective as an existing one. This conclusion aligns with traditional tort law principles, our precedent, and the realities of the pharmaceutical industry. I therefore respectfully dissent.

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[1] All subsequent references are to the Civil Code unless otherwise specified.

I. FACTUAL BACKGROUND

Where, as here, "a motion for summary judgment is used to test whether the complaint states a cause of action, the court will apply the rule applicable to demurrers and accept the allegations of the complaint as true." (*American Airlines, Inc. v. County of San Mateo* (1996) 12 Cal.4th 1110, 1118.) The plaintiffs' complaint thus offers the relevant facts. In 1991, Gilead Sciences, Inc. (Gilead), obtained an exclusive license to develop, manufacture, and sell tenofovir, an antiretroviral medication, as a treatment for HIV/AIDs. Tenofovir produces rapid and severe decline in kidney function when injected directly into the body, but it is ineffective when consumed orally. Gilead therefore developed an alternative form of the chemical, tenofovir disoproxil fumarate (TDF) that could be a usable medication when administered orally. In 1997, Gilead applied for approval to begin human clinical testing of TDF, which was approved by the Food and Drug Administration (FDA) in October 2001.

Despite the alternative form, TDF still has the potential for harmful side effects. At some point in TDF's development, Gilead developed a different form of tenofovir, tenofovir alafenamide fumarate (TAF), which Gilead formulated to be as effective as TDF at a lower dosage than TDF.

In November 2001, Gilead obtained permission to begin clinical testing of TAF. It conducted a combined phase I/II trial to compare the safety and effectiveness of TAF relative to TDF. Plaintiffs allege that Gilead's trial confirmed what preclinical research had shown — that TAF was just as effective as TDF but with lowered risks of renal, bone, and tooth injuries. As a result of this research, plaintiffs allege that Gilead knew that

TAF was as efficacious as and less toxic to kidneys and bones than TDF.

Despite this knowledge, Gilead discontinued TAF development in 2004, allegedly because it believed TAF would cannibalize TDF's sales. According to plaintiffs' complaint, Gilead chose to wait until TDF's patent expired before bringing TAF to market in order to maximize profits on both drugs. Gilead resumed testing of TAF in 2010 and obtained FDA approval in 2015. Gilead's TDF patent expired in 2017.

Plaintiffs presented evidence that, from 2001 through 2021, Gilead generated $101.8 billion in revenue from the sale of its tenofovir-based HIV drugs. TDF's annual revenues peaked at $10.7 billion dollars in 2016, declining every year after. As TDF revenue declined, TAF revenues increased every year from its release in 2015. In total, Gilead generated $53.7 billion in revenue from the sale of TAF-based drugs from its release in 2015 through 2021.

Plaintiffs do not contend that TDF is defective or that Gilead should have withdrawn it from the market. Instead, plaintiffs assert that Gilead unreasonably 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 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 Gilead made TAF available sooner.

Gilead moved for summary judgment on plaintiffs' claims for negligence and fraudulent concealment. The trial court denied Gilead's motion on both counts. The Court of Appeal reversed the denial of summary adjudication as to the fraudulent concealment claim but affirmed the denial of

summary adjudication of plaintiffs' 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." (*Gilead Tenofovir Cases* (2024) 98 Cal.App.5th 911, 917 (*Gilead*).) The court further concluded that, on the record before it, Gilead could not justify a narrower exception to the general duty of care. (*Ibid.*)

II. LEGAL BACKGROUND

Section 1714 "establishes a default duty requiring all persons and entities to exercise reasonable care to avoid causing harm to others." (Maj. opn., *ante*, at p. 2.) This duty forms the basis for the general negligence rule that persons and entities are generally " ' "liable for injuries caused by [their] failure to exercise reasonable care. (*Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 771 (*Cabral*).) "[T]he law imposes a general duty of care on a defendant only when it is the defendant who has ' " created a risk" ' " of harm to the plaintiff, including situations in which " ' "the defendant is responsible for making the plaintiff's position worse." ' " (*Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 214 (*USA Taekwondo*).)

Gilead has argued that it should be exempted from this standard. In evaluating such a request, courts ask whether the party can justify the judicial creation of a carveout from the default duty of care. (*Cabral*, *supra*, 51 Cal.4th at p. 783.) In *Rowland v. Christian* (1968) 69 Cal.2d 108 (*Rowland*), this court affirmed the default duty of reasonable care that is applicable to everyone. (*Id.* at p. 112.) It also "identified several considerations that, when balanced together, may justify a departure from the fundamental principle embodied in Civil Code section 1714." (*Cabral*, at p. 771.) The *Rowland* analysis

"is conducted 'at a relatively broad level of factual generality.' " (*Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1021 (*Kuciemba*).)

The *Rowland* factors fall into two categories focusing on foreseeability and public policy concerns. "Three factors — foreseeability, certainty, and the connection between the plaintiff and the defendant — address the foreseeability of the relevant injury, while the other four — moral blame, preventing future harm, burden, and availability of insurance — take into account public policy concerns that might support excluding certain kinds of plaintiffs or injuries from relief." (*Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1145 (*Kesner*).) Issues related to foreseeability are assessed on the basis of information available at the time of the alleged negligence, while " 'our duty analysis is forward-looking' in regard to policy issues surrounding burdens that would be placed on defendants." (*Kuciemba, supra*, 14 Cal.5th at p. 1022.)

The majority concludes that when a drug manufacturer allegedly has information indicating that a drug is equally effective and safer than a drug already on the market but elects to delay development of the alternative to maximize profit, an exception to the standard duty of care should exist. Such an exception is not justified.

A. The existence of a duty does not equate to a finding of liability.

We analyze the *Rowland* factors to determine " 'not whether they support an exception to the general duty of reasonable care on the facts of the particular case before us, but whether carving out an entire category of cases from that general duty rule is justified by clear considerations of policy.' " (*Kuciemba*, *supra*, 14 Cal.5th at p. 1021; see *id.* at p. 1018 [The

default duty of reasonable care remains the "starting point of our duty analysis."].)

We have previously emphasized the clear distinction between duty and liability. Because our task is to examine whether a categorical no-duty rule is appropriate, we must take a general view, rather than one bounded by the facts of the case. (See *Cabral*, *supra*, 51 Cal. 4th at p. 772.) Adhering to this approach is sometimes challenging because of the overlap between the *Rowland* factors and the relevant negligence elements. For example, "[w]hile the court deciding duty assesses the foreseeability of injury from 'the category of negligent conduct at issue,' if the defendant did owe the plaintiff a duty of ordinary care the jury 'may consider the likelihood or foreseeability of injury in determining whether, in fact, the particular defendant's conduct was negligent in the first place.' " (*Id.* at p. 773.) Given the potential to conflate the existence of a duty with a possible finding of liability, courts must be vigilant in applying the correct frame of analysis. Both Gilead and the majority fail to do so.

First, Gilead's request and much of the majority's reasoning rely on conjecture about calamitous liability for Gilead and other pharmaceutical manufacturers. These arguments misunderstand the fundamental issue. Rejecting an exception to the default duty does not signal anything about the merits of plaintiff's underlying case. Assuming the existence of a duty would automatically or even likely result in a finding of liability is contrary to the reality of tort litigation. For example, we have recognized for decades that restaurants can be liable for the negligent preparation of food. (See *Mexicali Rose v. Superior Court* (1992) 1 Cal.4th 617, 631.) Affirming this statutory default has not resulted in repeated or ruinous

liability for commercial restaurants. (See *id.* at p. 632 [noting this rule "corresponds to modern developments in tort law," particularly "our modern emphasis" on section 1714's requirement that "all persons . . . use ordinary care to prevent injuries as the result of their conduct."].) As discussed below, pharmaceutical manufacturers have been subject to the negligence standard of care in other jurisdictions. Yet, Gilead has not shown that manufacturers have been held to unfair standards nor has it presented any evidence that societally beneficial activity has ceased.

Second, Gilead and the majority contradict the procedural posture of this case, as well as the categorical approach required by *Rowland*, by contesting the issue of Gilead's actual knowledge of TAF's safety and efficacy. The majority concludes without a factual finding on this issue that a drug manufacturer cannot have actual knowledge of the safety and efficacy of an alternative before phase III testing. (E.g., maj. opn., *ante*, at pp. 17–19, 24.) By inappropriately deciding a key factual question at this phase of the litigation, the majority compounds its errors in analyzing foreseeability and public policy, as discussed below. The question of knowledge is further misplaced when one considers the breadth of the immunity granted by the majority. The majority's *Rowland* analysis appears to foreclose potential liability even after phase III testing, when actual knowledge is, in their view, possible.

As required by *Rowland*, the question here is merely whether an exception to the default duty of care is warranted where a pharmaceutical manufacturer has actual knowledge of a safer and equally effective alternative drug but chooses to delay the development of that alternative in order to maximize profit. The existence of a default duty of reasonable care does

not, as the majority fears, equate to a finding of negligence liability on these facts.

B. Gilead cannot clearly define the scope of its proposed exception.

Gilead argues that pharmaceutical manufacturers cannot know when a duty of care "arises" in the development process. It therefore concludes that the Court of Appeal erred in imposing an "unbounded" duty to develop safer alternatives. As an initial matter, this argument misunderstands that section 1714 imposes a universal duty to act reasonably to avoid harm. The lack of clarity around when a duty would "arise" weighs against Gilead's proposed exception. " 'No-duty rules are appropriate only when a court can promulgate relatively clear, categorical, bright-line rules of law applicable to a general class of cases.' " (*Kesner*, *supra*, 1 Cal.5th at p. 1144, quoting Rest.3d Torts, Liability for Physical and Emotional Harm, § 7, com. *a*, p. 78.) The absence of any "clear limiting principle" (maj. opn., *ante*, at p. 20) is unnecessary where a default rule exists.

Gilead still argues that a knowledge limitation is necessary to bound a pharmaceutical company's duty to its consumers when making development decisions. Gilead, however, does not show that a drug manufacturer could *never* have actual knowledge that an alternative drug is equally as effective as a currently available one after phase II testing (much less after phase III testing). Gilead merely relies on untested evidence presented by amici curiae and inferences from the federal regulatory framework. (See maj. opn., *ante*, at pp. 17–19.) Because, as the majority opinion notes, pharmaceutical development is a complex and specialized field, a definitive pronouncement that knowledge is impossible at this stage is inappropriate. Gilead's proposed "narrow" exception

therefore does not create a general class based on relevant markers like knowledge or culpability. Instead, Gilead proposes, and the majority accepts, an amorphous carveout for essentially all development decisions no matter how unreasonable they may be.

This is despite the fact that plaintiffs' claim is based on a duty that exists in the latter stages of development, once a drug has been "invented" and the manufacturer has done sufficient testing to gain (assumedly) actual knowledge of its effectiveness. The Court of Appeal therefore correctly focused on the later stages of development. (See *Gilead*, *supra*, 98 Cal.App.5th at p. 921, fn. 3 ["We use the term 'invent' here, rather than 'develop,' because the meaning of 'develop' in the pharmaceutical context is ambiguous. Gilead refers to the entire process of drug creation, from invention through FDA approval, as drug development. Because plaintiffs' claim is focused only on the latter stages of this process, Gilead's general reference to a 'duty to develop' obscures the precise nature of plaintiffs' claim."].) "While we agree with Gilead that a duty that placed manufacturers 'under an endless obligation to pursue *ever-better* new products or improvements to existing products' would be unworkable and unwarranted," plaintiffs are not pursuing liability under such a broad duty. (*Id.* at p. 921.) The majority, nonetheless, appears to have foreclosed further development of any standards in favor of total immunity from negligence related to drug development.

Plaintiffs do not contend that Gilead was obligated to develop TAF in its entirety — instead, they argue Gilead acted unreasonably when it paused development after promising early-phase results to protect their monopoly and maximize profits. Therefore, the issue of knowledge is not as dispositive

as Gilead believes. I agree with the Court of Appeal that the mere *possibility* of knowledge is a question better left to a fact finder, and should not be a basis for the creation of a categorical no-duty rule.

C. The default duty applies across other complicated contexts and industries.

Because the duty to minimize harm and the accompanying reasonableness standard apply across a wide range of factual scenarios, many just as or more complicated than drug development, Gilead's and the majority's concerns about hindsight bias do not justify an exception. California law routinely entrusts fact finders with reasonableness determinations in specialized or causally complex settings involving intricate technical evidence, multiple parties, regulatory bodies, and long timelines, using expert testimony and tailored instructions where needed. For example, in complex medical malpractice cases, even where the standard of care is "peculiarly within the knowledge of experts" the question remains one of fact. (*Landeros v. Flood* (1976) 17 Cal.3d 399, 410; see also *ibid.* ["[N]either this nor any other court possesses the specialized knowledge necessary to resolve the issue as a matter of law."].) We have rejected the argument that uncertain or conflicting scientific evidence justifies a departure from the reasonable care standard. (*Tarasoff v. Regents of University of California* (1976) 17 Cal.3d 425, 437–438; see *id.* at p. 438 [holding that although therapists argued they were unable to accurately predict whether patients will act violently, they must still "exercise 'that reasonable degree of skill, knowledge, and care ordinarily possessed and exercised by members of [that professional specialty] under similar circumstances' "].)

Similarly, we have affirmed that in asbestos litigation, even with long latency periods, multiple products, and scientific uncertainties, traditional substantial-factor causation is a question best left to a jury. (*Rutherford v. Owens-Illinois, Inc.* (1997) 16 Cal.4th 953, 975–978.) And, in multiparty construction and workplace accident cases, juries routinely review blueprints, safety logs and reports, sift through decades of internal corporate documentation, evaluate contradictory expert testimony, review state and federal regulations and inspection reports, and determine complex theories of causation. (See, e.g., *Elsner v. Uveges* (2004) 34 Cal.4th 915, 923 [discussing the admissibility of California Occupational Safety and Health Act of 1973's (Lab. Code, § 6300 et seq.) provisions in evaluating negligence actions].) We trust them to do so rather than simply providing broad immunity from liability.

Our previous decisions applying *Rowland* confirm that factual complexity does not support a carveout from the default duty of care. In *Kesner*, *supra*, 1 Cal.5th at page 1140, we affirmed that employers and landowners must exercise reasonable care in preventing secondary exposure to asbestos. (See also *id.* at p. 1147 ["[D]efendants cite no authority requiring a scientific consensus to establish foreseeability in the context of duty analysis."].) Similarly, in *T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145 (*Novartis*), we reaffirmed that fact finders are in the best position to evaluate the reasonableness of a pharmaceutical company's conduct in creating warning labels on its products. (See *id.* at p. 192.)

Drug manufacturing is no different. While pharmaceuticals are heavily regulated public goods, they are not so complicated as to be beyond a reasonableness standard. Gilead and the majority assert that the pharmaceutical industry

is exceptional in its development process, requiring "complex strategic decisions about where to devote finite resources based on limited information." (Maj. opn., *ante*, at p. 40.) Gilead and the majority, however, recognize that a drug manufacturer can be liable in defect. Defect claims are incredibly complex, requiring fact finders to sift through potentially contradictory scientific evidence and to evaluate iterative decisionmaking. Yet California law still empowers juries to make these determinations. Decisions related to drug development are no more complicated than those related to whether or not a drug is defective. The analysis in both contexts requires the "retrospective evaluations of reasonableness" the majority here eschews as completely unworkable. (*Ibid.*)

It is unclear why the majority suddenly doubts the ability of fact finders to make reasonableness determinations in this context. (E.g., maj. opn., *ante*, at p. 41 ["This retrospective inquiry creates a substantial risk that hindsight will supplant the manufacturer's contemporaneous judgment, even when its decisions were reasonable when made."].) By this same logic, all complicated business decisions should be freed from the hindsight risk of fact finders. Despite the risk of hindsight bias, California law, however, has long allocated these questions of liability to juries, not to courts.

III. *ROWLAND* FACTORS

Contrary to the majority's conclusion, the *Rowland* factors weigh against the creation of a carveout from the default duty of reasonable care. The harm from intentionally and unreasonably delaying the release of an equally effective but safer drug is foreseeable, and public policy supports preserving the default protections against negligent conduct.

Rowland reinforced "that the basic policy of this state set forth by the Legislature in section 1714 of the Civil Code is that everyone is responsible for an injury caused to another" by their conduct. (*Rowland*, *supra*, 69 Cal.2d at pp. 118–119.) The majority claims "it makes little sense to premise an entirely new form of liability" on limited precedent. (Maj. opn., *ante*, at p. 46.) This framing, however, subverts not only *Rowland*, but also California negligence law, as codified by the Legislature. (See *Rowland*, at p. 112 ["[I]t is clear that in the absence of [a] statutory provision declaring an exception to the fundamental principle enunciated by section 1714 of the Civil Code, no such exception should be made unless clearly supported by public policy."].)

Unlike the majority, I would not foreclose an entire category of negligence cases based on conjectural claims of harm, nor on plaintiff's "failure" to point to other cases where pharmaceutical manufacturers were found liable for the exact conduct alleged in plaintiff's complaint. Recognizing the default duty of care does not depend on previously proven violations of that duty. Instead, we should look to basic negligence principles.

We have never before held that drug manufacturers are entitled to an exception to the default negligence duty of care. The majority today applies *Rowland* with undue deference to the pharmaceutical industry to the peril of vulnerable and captive patients. I fear its broad reasoning, while purporting to be cabined by the facts of this case, risks diluting the "traditional" negligence claims it avers are left untouched. (Maj. opn., *ante*, at p. 55.)

A. The harm to plaintiffs is foreseeable.

Rowland's foreseeability factors do not support exempting Gilead from the default duty to act reasonably. Because Gilead has a monopoly over the research, development, and sale of tenofovir-based medications, its conduct was necessarily the root cause of plaintiffs' alleged harm. Despite Gilead's attempts to contest knowledge and offer hypothetical alternative causes, Gilead's decision to delay the development of TAF was the first step in plaintiffs' continued exposure to harmful side effects. In a different factual scenario, a pharmaceutical manufacturer might show that the FDA denied approval or some other roadblock arose. Gilead, however, asks — and the majority agrees — to exempt Gilead from any scrutiny related to the reasonableness of its actions. Gilead claims it is functionally powerless to control its own development cycle, and therefore blameless when it allegedly prioritizes profit over preventing harm. This argument contradicts both logic and our precedents.

"Regardless of alternative sources of [harm], or variations in the personal precautions [plaintiffs] undertake, it is plainly foreseeable" that negligent conduct can lead to harm. (*Kuciemba, supra*, 14 Cal.5th at p. 1025.) "An intervening third party's actions that are 'themselves derivative of defendants' allegedly negligent conduct . . . do not diminish the closeness of the connection between defendant's conduct and plaintiff's injury for purposes of determining the existence of a duty of care.' " (*Kesner*, *supra*, 1 Cal.5th at p. 1148, quoting *Beacon Residential Community Assn. v. Skidmore, Owings & Merrill LLP* (2014) 59 Cal.4th 568, 583.)

Particularly relevant in the foreseeability analysis is the element of control by the would-be defendant over the source of harm. (*Novartis*, *supra*, 4 Cal.5th at p. 168.) In *Novartis*, we

declined to create an exception from the typical duty to warn because federal regulations granted the brand-name drug manufacturer exclusive control over the active ingredients in the generic drug and the content of the warnings included in the generic's label. (*Ibid*.) So too here, Gilead had complete control not only over the development and release of TAF, but also all other tenofovir-based medications. The "intervening conduct" is "predictable and derivative of the alleged misconduct," thus weighing against an exception. (*Kesner*, *supra*, 1 Cal.5th at p. 1149.)

Gilead argues that it could not have actual knowledge of TAF's safety and efficacy until full FDA approval, thus making plaintiff's harm too attenuated. As discussed above, at this stage of the litigation, a court should not substitute its decision-making for that of a better-informed fact finder on the issue of knowledge, and whether such knowledge is possible. Further, it is unclear why FDA approval would provide a drug manufacturer with additional knowledge of safety and efficacy, given that the manufacturer is the one furnishing the FDA with the safety and efficacy data the agency considers. (See maj. opn., *ante*, at p. 19; 21 U.S.C. § 355(d).)

The very purpose of *Rowland* is to determine whether a modest carveout to the general duty of care is justified. (*Rowland*, *supra*, 69 Cal.2d at p. 112.) The majority argues that reserving the question of knowledge for a fact finder would render the foreseeability inquiry moot. (Maj. opn., *ante*, at pp. 25–26.) While the question of foreseeability is a matter of law, we have previously declined to make such a determination based on contested facts. (See, *Kesner*, *supra*, 1 Cal.5th at p. 1147.) *Rowland* encourages judicial modesty in making these determinations. I would not, as the majority chooses, decide

that drug manufacturers as a class can *never* know that an alternative drug is safer than an existing one at the stage of research and development at issue, much less at a later one.

The majority further justifies its decision to provide broad immunity to Gilead by speculating that any harm to plaintiffs might be exacerbated by causes other than Gilead. (Maj. opn., *ante*, at pp. 23–26.) To be sure, plaintiffs' category of alleged injury — continued, unnecessary exposure to devastating side effects — could be worsened by other events or by the conduct or choices of third parties. But, again, such determinations should be addressed on the facts at the liability stage, rather than through the creation of a categorical no-duty rule. This is particularly true given *Rowland*'s purpose of identifying only narrow exceptions where warranted. (See *Kuciemba*, *supra,* 14 Cal.5th at p. 1021 [*Rowland* asks " 'not whether [the factors] support an exception to the general duty of reasonable care on the facts of the particular case before us, but whether carving out an entire category of cases from that general duty rule is justified by clear considerations of policy.' "].) "We have no occasion to address other arguments defendants might make to defeat liability. It must be remembered that a finding of duty is not a finding of liability." (*Kesner*, *supra,* 1 Cal.5th at p. 1157.) Gilead should be free to raise challenges to causation at a later stage, but these conjectural, alternative causes of harm do not warrant a categorical exception to the default duty of care.

B. The category of conduct is morally blameworthy.

Contrary to the majority's conclusion, *Rowland*'s public policy factors do not support exempting Gilead from the default duty to act reasonably. Plaintiffs allege that Gilead alone, by pausing TAF development, caused them harm. At a categorical

level, unreasonably delaying the development of a safer and equally effective alternative drug is morally blameworthy. We have regularly recognized that "[t]he overall policy of preventing future harm is ordinarily served, in tort law, by imposing the costs of negligent conduct upon those responsible." (*Cabral*, *supra*, 51 Cal.4th at p. 781.) As in *Novartis*, a drug manufacturer with exclusive rights to develop the safer alternative formulation of a drug is not only in the best position to take action, but also is the *only* entity with the ability to prevent plaintiffs' alleged unnecessarily prolonged exposure to these side effects. (See *Novartis*, *supra*, 4 Cal.5th at pp. 168–169.)

Gilead argues that " 'the moral blame that attends ordinary negligence is generally not sufficient to tip the balance of the *Rowland* factors in favor of liability.' " (Maj. opn., *ante*, at p. 33, quoting *Adams v. City of Fremont* (1998) 68 Cal.App.4th 243, 270, disapproved of on another ground by *USA Taekwondo*, *supra*, 11 Cal.5th 204.) The allegedly unreasonable conduct here, however, goes beyond ordinary negligence.

Because drug manufacturers financially benefit from the significant power imbalance between themselves and TDF patients when prioritizing or delaying certain drugs for development, this factor weighs against recognizing an exception. "[M]oral blame is typically found when the defendant reaps a financial benefit from the risks it has created. (*Kuciemba, supra,* 14 Cal.5th at p. 1025.) As discussed, Gilead has made over $100 billion from tenofovir-based medications, profits allegedly increased by the intentionally delayed release of TAF in 2015, two years before its patent on TDF expired.

Further, "[w]e have previously assigned moral blame, and we have relied in part on that blame in finding a duty, in

instances where the plaintiffs are particularly powerless or unsophisticated compared to the defendants or where the defendants exercised greater control over the risks at issue." (*Kesner*, *supra*, 1 Cal.5th at p. 1151.) The majority rejects plaintiffs' showing on these points, instead relying again on its factual conclusion that Gilead could not have had actual knowledge of TAF's safety and efficacy. Then, paradoxically, the majority claims a categorical approach, noting that the precise motivations attributed to the defendant do not weigh on the moral blameworthiness of conduct. (Maj. opn., *ante*, at p. 34.) This argument is contrary to the holdings of *Kuciemba* and *Kesner*, where blameworthiness was attributed, at least in part, based on the reaping of a profit and inherent power imbalance between plaintiffs and defendants.

It is true that some manufacturers, including Gilead, could have justifiable, even laudatory reasons for delaying the development of an alternative treatment. However, specific challenges to liability are not relevant when a party seeks a categorical rule. (*Kesner*, *supra,* 1 Cal.5th at p. 1157.) Defendants like Gilead have considerable profit incentives to extend the lives of their patents. At the same time, drug manufacturers have a unique form of control stemming from patent protections over entire compounds. Potential plaintiffs are particularly vulnerable where, as here, they need the lifesaving tenofovir compound, available from only one manufacturer. Defendants should be able to demonstrate the reasonableness, neutrality, or societal benefits of delay, if they exist, during later stages of litigation. The majority's categorical exemption, however, does not allow any negligence case against drug manufacturers to reach the merits, no matter how

unreasonably the manufacturer may have acted or how much harm they may have caused.

The majority is concerned that considering profit and power, as required by our precedents, would weigh against an exception to the duty of care in "virtually every negligence action brought against a business." (Maj. opn., *ante*, at p. 35.) This is a feature of the *Rowland* analysis, not a bug. By framing the duty of reasonable care as a universal default duty, *Rowland* moved away from status-based privilege to prioritize protecting people from preventable injuries. (See *Rowland*, *supra*, 69 Cal.2d at pp. 118–119 ["[T]he basic policy of this state set forth by the Legislature in section 1714 of the Civil Code is that everyone is responsible for an injury caused to another" by their conduct.].) Thus, it is unsurprising that allegedly negligent conduct by a large, profitable company when compared to captive consumers with little power would be found morally blameworthy. This is not a " 'heads I win, tails you lose' " (maj. opn., *ante*, at p. 54) exercise as the majority alleges but rather a recognition of *Rowland*'s shift towards making negligence claims more accessible.

Gilead and the majority make much of the ameliorative steps a manufacturer would need to take to bring a product like TAF to market. (Maj. opn., *ante*, at pp. 35–36.) However, plaintiffs are not claiming that Gilead was required to release a safer alternative to TDF. Rather, they claim Gilead intentionally and unreasonably delayed the development of a safer, more effective alternative drug that they had already created. If a manufacturer were to reach a roadblock, such as contradictory results in a later trial or failure to secure FDA approval, they would not be required to go above and beyond the

ordinary standard of care. Instead, manufacturers need only reasonable justifications for pausing development.

Blameworthiness under *Rowland* arises because of the profit motive and power imbalance inherent in a pharmaceutical monopoly. Gilead "created the risk of harm to plaintiffs by selling TDF, a drug with harmful side effects." (*Gilead*, *supra*, 98 Cal.App.5th at p. 935.) And Gilead made " ' "plaintiffs' position worse" ' " (*USA Taekwondo*, *supra*, 11 Cal.5th at p. 214) by allegedly deliberately and unreasonably pausing for almost a decade the development of an alternative drug without the same adverse effects, in order to reap substantial profits.

C. The societal costs of the default duty of care are outweighed by the benefits of ensuring reasonable conduct.

Gilead requests that all pharmaceutical manufacturers be immunized from negligence liability stemming from their development decisions, with no regard to consumer harm. Again, we are meant to analyze the *Rowland* factors to determine " 'not whether they support an exception to the general duty of reasonable care on the facts of the particular case before us, but whether carving out an entire category of cases from that general duty rule is justified by *clear* considerations of policy.' " (*Kuciemba*, *supra,* 14 Cal.5th at p. 1021, italics added.) Contrary to the majority's conclusion, Gilead does not meet this standard, and the default duty of care should therefore stand.

These factors require that we weigh necessarily uncertain policy considerations. (E.g., *Kuciemba, supra*, 14 Cal.5th at p. 1022 [" '[O]ur duty analysis is forward-looking' in regard to policy issues."].) What the majority calls a "vain exercise" (maj. opn., *ante*, at p. 55) is required to hold Gilead to the proper

burden of persuasion. (See *Cabral*, *supra*, 51 Cal.4th at p. 771 ["[C]ourts should create [an exception] only where 'clearly supported by public policy.' "].)

Both this opinion and the majority's make assumptions about how parties will behave in the future. The difference is I do not believe speculation, much of which we have previously rejected, tips the *Rowland* factors in favor of additional immunity for the pharmaceutical industry. (*Novartis*, *supra*, 4 Cal.5th at p. 173 ["We are equally unpersuaded by Novartis's contention that warning label liability would stifle innovation by substantially raising drug costs and chilling the development and marketing of new drugs."].) The *Rowland* factors impose the same standard on any party seeking a categorical no-duty rule. That standard requires more than the specter of widespread liability. (E.g., *Novartis*, at pp. 173–175 [rejecting the argument that the default negligence duty would expose brand-name manufacturers to limitless liability because the ordinary limiting principles on negligence claims remain].) I would follow our precedent and find that the costs, both to the public and to potential defendants, are outweighed or otherwise too hypothetical to support an exception to the default duty of care.

This conclusion reflects the reality of the pharmaceutical industry. Gilead and other manufacturers are incentivized to maximize the lifespan of their patents to extend their monopoly over brand-name sales. (Hickey & Ward, Congressional Research Service, The Role of Patents and Regulatory Exclusivities in Drug Pricing (Jan. 30, 2024) (Hickey & Ward) <https://www.congress.gov/crs-product/R46679> [as of Aug. 3, 2026] ["Because the exclusivity that IP rights provide may enable the rights holder (e.g., a brand-name drug manufacturer)

to charge higher-than-competitive prices for a period of time, rights holders may have an incentive to lengthen that time period as much as possible."]; all Internet citations in this opinion are archived by year, docket number and case name at <https://courts.ca.gov/opinions/cited-supreme-court-opinions>.) The majority, however, accepts without question that "drug manufacturers already have 'ample incentive[s] to release safer products into the marketplace,' including the opportunity to gain market share and avoid reputational harm associated with adverse effects." (Maj. opn., *ante*, at p. 37.) It therefore concludes that this existing profit-motive structure undermines the need to "impose" a tort duty to ensure reasonable decisionmaking about whether and when to develop safer alternative drugs. (*Ibid.*)

Decades of litigation and regulation, particularly in the antitrust context, contradict this assumption that drug makers are adequately incentivized to release safe and effective drugs as quickly as possible. (See, e.g., *FTC v. Actavis, Inc.*, (2013) 570 U.S. 136, 140 [Federal Trade Commission action targeting reverse payment settlements, under which a patentee agrees to pay a potential generic manufacturer not to produce a version of the drug until the patent's term expires].) Where, as here, the manufacturer has an exclusive patent on the existing product and its related formulations, negligence liability serves as one of the few safeguards against unreasonable conduct.

Keeping in mind the level of generality we must utilize in the *Rowland* test, I believe the question is whether there is a societal benefit or cost to maintaining the default duty when a drug manufacturer has the exclusive patent on a drug and its similar formulations. Because this monopoly posture means the traditional incentives do not apply here, I would find the default

duty of reasonable care is a necessary safeguard against harmful conduct — a purpose it was designed to serve.

Because of the societal benefits of drug development, we have in the past excepted pharmaceutical manufacturers from certain kinds of liability. Gilead fails, however, to justify an additional and especially broad exception, particularly in light of these pre-existing carveouts. In *Brown v. Superior Court* (1988) 44 Cal.3d 1049 (*Brown*), we exempted prescription drug manufacturers from strict liability based on the societal cost of such a duty. (*Id.* at p. 1063.) We reasoned that the risk of strict liability could discourage research and development of beneficial pharmaceuticals or force companies to conduct additional, unnecessary testing before releasing a drug to market. (*Ibid.*) By contrast, a duty here would not disincentivize the development of drugs but merely allow for the possibility of liability when the development of less harmful alternatives is unreasonably delayed in order to maximize profit. Imposing strict liability, which significantly lowers a plaintiff's burden, presents a heightened chance of finding actual fault — a concern not found here, where plaintiffs still must prove negligence. The application of the default duty of care would simply encourage companies to take consumer harm into reasonable account when making development decisions.

Additionally, the risk of disincentivizing the development of new drugs or drug formulations is too hypothetical to support a categorical exemption from liability. Drug makers have long claimed that any risk of liability would discourage innovation or shutter entire companies. Gilead, however, overstates the empirical support for this claim, as long-term studies of the economic effects of tort liability for pharmaceuticals present contradictory evidence. (See Garber, Economic Effects of

Product Liability and Other Litigation Involving the Safety and Effectiveness of Pharmaceuticals (RAND Institute for Civil Justice, 2013) p. 62 (RAND Study) ["Both proponents and opponents of preemption have cogent arguments and/or empirical evidence to support at least some of their claims about economics effects. Thus, it appears that there are both substantial social benefits and substantial social costs of . . . litigation. We cannot, however, compare the social benefits and costs quantitatively."].) Such conjecture cannot support an exception.

For example, Gilead argues that instead of researching new cures for perhaps rarer or less-studied conditions, it will be forced to develop alternatives to existing treatments. (See, e.g., maj. opn., *ante*, at p. 43 ["[T]he duty may encourage manufacturers to focus on making marginal improvements to existing drugs rather than pursuing novel therapies for diseases that lack effective treatment."].) In its discussion on treatments for rarer conditions, the RAND Study concluded that "it seems likely that even if product liability deters some product-development efforts, product liability exposure is unlikely to tip the balance in many cases." (RAND Study, *supra*, at p. 55.) Because fairly small markets are a "defining characteristic" of these types of drugs, "it seems likely that there would typically be insufficient financial incentives to induce companies to invest in drug development even if there were no liability exposure." (*Ibid*.)

Some evidence, moreover, supports positive societal effects from tort liability. Research has suggested that "the potential for litigation to uncover inappropriate corporate behavior increases the potential costs of engaging in such behavior and thus, at least in theory, will tend to deter

manufacturers from engaging in such practices." (RAND Study, *supra*, at p. 60; see also *ibid.* [discussing one study that examined "examples of alleged practices — such as failing to report adverse events to the FDA, downplaying the extent or severity of side effects, failing to make clinical trial data public, and delaying public reports of adverse events"].) Despite such mixed empirical evidence, the majority accepts wholesale Gilead and amici curiae's unsupported claim that innovation will be stifled by the mere risk of liability for negligence.

The majority's acquiescence is further surprising considering that we recently declined to create a categorical no-duty rule based on nearly identical speculative "burdens" on pharmaceutical innovation. (*Novartis*, *supra*, 4 Cal.5th at p. 173.) We noted that the pharmaceutical company in that matter offered " 'no clear or sufficient basis for concluding that research and development will inevitably decrease' " and no evidence that drug innovation had declined in the decades that drug manufacturers were exposed to strict liability for failure to warn. (*Ibid.*) Accordingly, we held that this factor did not support an exception to the default duty of care. (*Ibid.*) The majority attempts to distinguish *Novartis* by claiming that manufacturer conduct related to drug development is different than manufacturer conduct related to already available drugs. While the contexts may differ, it's unclear why we should countenance unreasonable, harmful conduct in one context but not the other, given California's strong public policy of protecting its residents from preventable injuries. (*Kuciemba*, *supra,* 14 Cal.5th at p. 1021 [requiring " 'clear considerations of policy' " to justify " 'carving out an entire category of cases from that general duty rule.' "].)

In any case, drug makers would need only to avoid unreasonable decisions regarding whether and when to commercialize a safer drug. Allocating resources to address a more pressing medical need instead of developing a safer alternative, for example, would almost certainly defeat a claim of negligence. As discussed above, Gilead and the majority, however, erroneously equate duty with liability. (See *Cabral*, *supra*, 51 Cal.4th at pp. 772–773.)

D. Pharmaceuticals are entirely unlike other consumer industries.

I find similarly unconvincing Gilead's and the majority's attempted analogies to other industries, including automobile manufacturing. Rejection of a carveout here has little, if any, relevance for other products or industries. For example, unlike drug makers, automobile manufacturers are not given a state-guaranteed monopoly on producing cars, nor on species of safety technology. Drivers are free to choose between different manufacturers and models. However, many drug consumers — including the HIV patients seeking relief here — have no choice but to purchase the brand-name medication because patent protections ensure no other option exists. As a result, drug manufacturers can charge higher-than-competitive prices for their products. This dynamic creates a unique incentive for pharmaceutical companies to extend their periods of exclusive sales. Drug companies have developed well-known tactics to extend these rights for as long as possible.[2]

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[2] "Such patenting practices include so-called (1) patent 'evergreening,' (2) 'product hopping,' (3) 'patent thickets,' and (4) 'pay-for-delay' settlements. Patent 'evergreening' is the alleged practice of filing for new patents on secondary features of a

While regulators have sometimes stepped in to punish or curtail such conduct, they have done so mostly in individual enforcement actions targeting antitrust violations. Of course, anticompetitive or anti-consumer behavior in the industry at large does not automatically entitle plaintiffs to relief. That said, it is an additional reason why a categorical exemption for the pharmaceutical industry is both unwarranted and unwise.

Apart from industry-wide distinctions in regulation, drugs themselves are unique. Plaintiffs here needed TDF to prevent HIV from reproducing and eventually contributing to their deaths. They could not decline the side effects, which are part and parcel of the life-saving drug. By contrast, users of products like cars can pay more for added safety features or abstain from purchasing a car altogether. Because of these product-specific considerations, leaving the default duty of reasonable care in place here is unlikely to have negative effects on other markets.

E. The burden on pharmaceutical manufacturers is negligible.

Drug manufacturers, denied an exception to the default duty of reasonable care, will not lose the profit incentive to

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pharmaceutical as earlier patents expire, thereby extending effective patent exclusivity past the original 20-year term. 'Product hopping' is the alleged practice of a brand manufacturer attempting to switch the market to a new, similar product covered by later-expiring patents before IP rights on an existing product expire. 'Patent thickets' refer to portfolios of numerous, overlapping patents on the same pharmaceutical, which allegedly deter competition due to the risk of infringement and the high cost of patent litigation. 'Pay-for-delay' or 'reverse payment' settlements resolve patent litigation through payments or other compensation from a brand to a generic or biosimilar manufacturer to delay generic market entry." (Hickey & Ward, *supra*, summary.)

develop better versions of their products, nor to develop novel therapies, if they are simply required to make reasonable decisions to minimize harm. They merely would "lose" the ability to time those decisions without regards to injury to consumers. This factor, accordingly, does not support an exception. The majority, on the other hand, concludes that maintaining the default duty to act reasonably would force manufacturers to devote significant time, money, and resources to developing and commercializing drugs they might not otherwise prioritize. (Maj. opn., *ante*, at pp. 43–45.)

Gilead fails to show that the default duty of care imposes any actual burden. Gilead could have acted exactly as it did here and be protected from liability if it behaved reasonably. Drug manufacturers theoretically have been subject to this default duty of care for decades and yet drug development (including the parallel testing of "backup" formulations) has not ground to a halt.

The opioid crisis and resulting litigation shed light on the insufficiency of Gilead's arguments. While opioid plaintiffs brought suit under several different theories of liability, in at least one case, the negligence claims brought by the State of Rhode Island against a group of opioid manufacturers survived summary judgment. The court there held that "[d]efendants owed duties to the State, including 'a duty to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs,' as well as 'a duty to exercise reasonable care . . . not to cause foreseeable harm to others.' " (*State v. Purdue Pharma L.P.* (R.I., Aug. 16, 2019, No. PC-2018-4555) 2019 WL 3991963, p. *16.) This acknowledgement of the default duty highlights the societal benefits of flexible tort liability. The opioid crisis has caused incalculable harms to

individuals, organizations, and public entities. The combination of litigation by private and public parties with governmental regulations started the long process of addressing these injuries and preventing future harm. (See also *Ohio County Commission v. Express Scripts, Inc.* (N.D.W.Va., Dec. 23, 2024, No. 5:24-CV-142) 2024 WL 5701504, p. *15 ["[P]laintiffs have identified that defendants owed duties to plaintiffs, including 'a duty to employ reasonable standards of care in the sale, delivery, dispensing, promotion, and gatekeeping control of the supply of highly addictive, dangerous opioids. This duty includes a duty to not create a foreseeable risk of harm or injury.' "].) Like opioid plaintiffs, the consumers here seek redress under the default general duty of care for defendant's alleged conduct in the development of tenofovir products. Given the role negligence liability has played in addressing the opioid epidemic, it is disappointing that the majority has provided such sweeping immunity to drug manufacturers.

Even assuming there would be a financial cost to defendants, such a cost likely would be small in comparison to profits as well as expected as part of their research and development process.[3] The burden here is importantly distinct from cases like *Verdugo v. Target Corp.* (2014) 59 Cal.4th 312. In contrast to training retail employees on a particular medical intervention (*id.* at p. 340), pharmaceutical companies already anticipate the costs of developing, researching, and testing new drugs. Since Gilead eventually paid the costs to conduct a phase

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[3] Plaintiffs submit evidence that at the end of 2003 Gilead had cash and marketable securities (effectively cash) of over $700 million. Gilead's internal documents indicated that the remaining costs for approval of TAF were estimated to be $82 million.

III trial, seek FDA approval, and market TAF, it is disingenuous to argue that the cost of further developing an alternative drug is an onerous burden that would otherwise not be incurred. Moreover, drug manufacturers directly benefit from the investment in research and development, as demonstrated by the more than $100 billion dollars Gilead has made from TDF and TAF-based drugs. Therefore, Gilead's alleged financial burden does not support a categorical no-duty rule.

For the same reasons, Gilead fails to show that difficulty accessing insurance supports an exception. (E.g., maj. opn., *ante*, at p. 52 ["[T]he duty would likely result in significantly greater liability exposure than the Court of Appeal perceived."].) The sky has not yet fallen on drug manufacturers, despite years of potential exposure to negligence liability for development decisions. Neither the majority nor Gilead offers " 'clear considerations of policy' " which justify " 'carving out an entire category of cases from that general duty rule.' " (*Kuciemba*, *supra,* 14 Cal.5th at p. 1021.)

IV. ALTERNATIVE AVENUES

The majority believes that its decision will not entirely insulate manufacturers from potential liability because plaintiffs have alternative avenues to seek redress. (Maj. opn., *ante*, at pp. 55–56.) Negligence liability, however, is plaintiffs' clearest avenue to compensation for their alleged injuries. Plaintiffs cannot adequately protect themselves via statutes prohibiting unlawful, unfair, fraudulent, or misleading conduct. They are seeking accountability for a company's alleged unreasonable prioritization of profit, conduct which purportedly harmed its captive consumer base of TDF users. They request compensation for their individual injuries allegedly caused by

many years of unnecessary exposure to devastating side effects. Their claim sounds clearly in negligence.

Although I understand my colleagues' wariness of potentially "modifying" incentives in such a complicated and crucial industry, I suggest that recognizing an exemption from the typical tort scheme is the far more disruptive outcome. The Pennsylvania Supreme Court, in declining to immunize pharmaceutical companies from negligence claims, noted that "Congress and the Legislature are in the best position to make these sorts of weighty and consequence-laden policymaking judgments impacting a traditional, state-law, civil, remedial scheme." (*Lance v. Wyeth* (2014) 624 Pa. 231, 277 [85 A.3d 434].)

In general, I tend to agree that regulation by other branches of government may be preferrable to civil liability. Regulatory measures, such as FDA review and approval of new drugs, however, cannot address the harm of manufacturers withholding safer alternatives.[4] (See maj. opn., *ante*, at p. 55.) Even assuming an overlap, public and private regulation can and should coexist, especially in the pharmaceutical context. State tort actions play a pivotal role " 'as a complementary form of drug regulation' with respect to drug labeling." (*Novartis*, *supra*, 4 Cal.5th at p. 169, quoting *Wyeth v. Levine* (2009) 555 U.S. 555, 578; see *Wyeth*, at p. 579 ["State tort suits uncover unknown drug hazards and provide incentives for drug

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[4] While drug safety oversight has been a core function of the FDA, recent changes in leadership, staffing, budget priorities, and policy direction have raised concerns about the continuing vitality and effectiveness of the regulatory framework. (See, e.g., Gottlieb, *Making the FDA Great Again* (June 18, 2026) JAMA Health Forum, vol. 7, No. 6 <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2850771> [as of Aug. 3, 2026].)

manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information."].) Regulations alone may not adequately protect consumers from harm. (See *Novartis*, at p. 169, citing *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 65.) Accordingly, plaintiffs should be able to plead their claim in negligence, as we have regularly confirmed that pharmaceutical companies are subject to such liability. (E.g., *Brown*, *supra*, 44 Cal.3d at p. 1069, fn. 12 [Manufacturers can and should still be liable "under general principles of negligence."].)

V. CONCLUSION

Today's decision provides sweeping immunity, allowing pharmaceutical companies to develop drugs without accounting for the risk of harm to consumers like plaintiffs here, who are held captive when a drug is both lifesaving and subject to exclusive manufacturing rights.

I urge the Legislature to consider whether pharmaceutical companies should have immunity from negligence liability no matter how unreasonably they may act or how much serious and avoidable harm they may cause patients when making decisions about commercializing drugs.

EVANS, J.

See next page for addresses and telephone numbers for counsel who argued in Supreme Court.

Name of Opinion Gilead Tenofovir Cases

Procedural Posture (see XX below)
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Original Proceeding
Review Granted (published) XX 98 Cal.App.5th 911
Review Granted (unpublished)
Rehearing Granted

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Judge: Andrew Y.S. Cheng

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