S283862

No. S283862

IN THE SUPREME COURT OF CALIFORNIA

GILEAD TENOFOVIR CASES

GILEAD SCIENCES, INC.,
Petitioner,
v.
SUPERIOR COURT OF THE CITY AND COUNTY OF SAN FRANCISCO,
Respondent;
and
PLAINTIFFS IN JCCP NO. 5043,
Real Parties in Interest.

Review of a decision from the Court of Appeal, First Appellate District, Division Four, No. A165558
San Francisco County Superior Court No. CJC-19-005043
Hon. Andrew Y.S. Cheng

PETITIONER'S OPENING BRIEF ON THE MERITS

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QUESTIONS PRESENTED

1. When a plaintiff sues a manufacturer claiming injury from the manufacturer's product, must the plaintiff prove that the product is defective?

2. Did the Court of Appeal err in concluding that a manufacturer of a non-defective product has a duty to develop, without delay, a different product that is safer for some consumers?

INTRODUCTION[1]

The Court of Appeal overrode a century of common law to impose on manufacturers a duty that no court anywhere in the country has ever suggested. Whereas the common law requires manufacturers to produce non-defective, reasonably safe products, the Court of Appeal has added a duty to develop and commercialize, without delay, a *different* product that is safer for some consumers. This duty weaponizes innovation across industries, undermining public welfare by inhibiting research and development of lifesaving and lifechanging products.

Gilead Sciences, Inc. invented HIV medicines based on a compound called "TDF," which helped transform HIV from a death sentence into a manageable chronic illness. No one disputes that in marketing the TDF medicines, Gilead fulfilled every previously recognized duty that a manufacturer owes to its

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[1] This brief cites the Court of Appeal opinion as "Op." and amicus letters and briefs as "____ Ltr." and "___ Br." according to the name of the lead amicus. "___ COA Br." denotes that the brief was filed in the Court of Appeal.

consumers: design and manufacture a reasonably safe product, and adequately warn of any known risks. Plaintiffs have never claimed there was any defect in the manufacturing process. There is no design defect because it is undisputed that the benefits of these lifesaving medicines vastly outweigh their risks. Like all medicines, TDF has side effects—albeit ones that affect a fraction of 1% of patients. But Plaintiffs have abandoned any claim that Gilead failed to warn of those side effects. That should have been the end of the matter.

The Court of Appeal, however, let Plaintiffs' negligence claim proceed, based on Gilead's decisions about a *different* compound, "TAF," which would later prove to lessen those side effects for some people. Gilead had investigated TAF as a backup to TDF. Preliminary data on TAF, however, showed it to be no safer than TDF and to carry *additional* potential side effects. So Gilead stopped TAF development in 2004 and focused on developing improved TDF-based medicines instead. Gilead's focus on TDF yielded groundbreaking therapies that FDA and the patient community had been requesting and which benefited the entire population of people living with HIV. But Plaintiffs contend that Gilead should have continued developing TAF.

The Court of Appeal found a duty to continue developing and to market a different product in Civil Code § 1714, a general negligence statute requiring all persons to exercise "ordinary care." The court believed that § 1714 imposes, and since its enactment in 1872 has always imposed, this additional duty on manufacturers—even though no court had ever recognized it. But

§ 1714 does not override painstakingly calibrated common-law rules, much less the entire body of products-liability law, which requires manufacturers simply to produce reasonably safe products—i.e., products free of defect in manufacturer, design, and warnings.

The Court of Appeal's dramatic departure from common law is unwarranted and unwise, as the many petition-stage amici attested. The defect requirement fully protects consumer safety—encouraging manufacturers to research and develop groundbreaking and improved new products, and to market only the reasonably safe ones. The Court of Appeal replaced it with a rule that provides no meaningful standard for assessing a manufacturer's conduct. The rule will make us all less safe. If manufacturers can be held liable upon acquiring information about a possible safer product, they will veto research projects directed at acquiring that information. Manufacturers will also prioritize marginal improvements to existing non-defective products to avoid litigation rather than breakthrough new products with far greater value to the public. And the duty will doom manufacturers to a no-win cycle of liability, transforming every product-development decision into a potential lawsuit over the path not taken—or taken, but allegedly not quickly enough. All this undermines consumer welfare—sacrificing affordability, choice, and the development of beneficial new products—without enhancing safety.

This Court should reject the Court of Appeal's duty.

STATEMENT OF THE CASE

Gilead Develops TDF, A Lifesaving HIV Medicine

This case is about medicines that helped transform HIV treatment. HIV was fatal through the 1990s. (1App.221-22, 228-31, 241-42.) Treatments were ineffective, complicated, and highly toxic. (1App.232-36, 249-53.) This was the bleak landscape Gilead confronted in 1991 as a small biotech company researching possible HIV medicines, including a compound called tenofovir. (1App.50, 340-41.)

It took six years of "preclinical" research—research in test tubes, petri dishes, and animals—for Gilead to discover a candidate promising and safe enough to test in humans: tenofovir disoproxil fumarate (TDF). (1App.45, 340-41; 4App.1253-83.) It took another four years of "clinical" research—trials in humans (here, well over a thousand patients)—to amass evidence sufficient for FDA approval of the first TDF medicine, Viread®, in October 2001. (1App.146, 201-02; 6App.1814-18.)

TDF proved to be a game changer: It enabled people with HIV to live normal lives with far less severe side effects. (1App.232-36.) Because of those astounding results, Gilead made TDF the backbone for a series of improved medicines. At the urging of FDA and the patient community, Gilead concentrated its finite resources on overcoming one of the most significant challenges to the effectiveness of HIV treatments: patient non-compliance. Patients had to take multiple medicines stored at different temperatures, on different schedules, including in the middle of the night. Many people could not keep up, resulting in

resistant strains that made the medicines totally ineffective. (6App.1968.) It was a matter of life and death. What people living with HIV desperately needed was a combination of medicines in a single pill that could be taken once a day. (See FDA, Guidance for Industry on Fixed Dose Combinations and Co-Packaged Drug Products for Treatment of HIV; Availability, 69 Fed.Reg. 28931 (May 19, 2004).)

It took five more years of research after Viread® for Gilead to achieve that breakthrough in 2006. (1App.201 [Atripla®].) FDA lauded it as a "watershed in HIV treatment." (FDA, *The History of FDA's Role in Preventing the Spread of HIV/AIDS* (Mar. 14, 2019), https://tinyurl.com/5ff32dyc.)

Like any medicine, TDF can have side effects. As relevant here, they include possible effects on bone density and kidney function. (1App.151; see, e.g., 2App.480, 487-88.) Those risks are remote, affecting 0.002% and 0.11% of patients, respectively, per year. (7App.2355, 2358-60.) From the beginning, an FDA-approved label has alerted patients and physicians to the potential side effects. (10App.3102.)

As Plaintiffs concede, Gilead provided FDA all necessary information about TDF, including its side effects, and FDA correctly found that each TDF medicine's benefits outweighed its risks. (10App.3099-103; COA.Arg.Tr. 41-44.) FDA has never withdrawn approval for any TDF medicine (10App.3103), reflecting that TDF remains safe, effective, and approved for use (see COA.Arg.Tr. 41). The U.S. Department of Health and Human Services and the World Health Organization still

recommend TDF as a first-line HIV therapy. (3App.991-95, 997, 1018-19.)

Gilead Investigates TAF As A Backup, But Stops TAF Development For Failing To Meet Benchmarks

As groundbreaking as TDF turned out to be, it was never a sure thing. Even with the most promising preclinical data, clinical trials are highly unpredictable: Fewer than one in eight candidates that start clinical trials ultimately obtain FDA approval. (Op. 43.) Backup candidates are therefore essential. So with TDF well into clinical trials, Gilead began investigating tenofovir alafenamide (TAF) in 1999. (3App.1171-88.)

TAF's preclinical results were mixed. More tenofovir appeared to reach target cells (which could be good), but more tenofovir also reached cells that were not targeted (which could be bad). (5App.1665-66, 1669, 1688, 1717-21; 7App.2292.) TAF also appeared to be more toxic than TDF in dogs and rats. (5App.1688.) A member of the development team warned of TAF's "potential toxicity" because it accumulated in bone. (5App.1723.) TAF's development was so far behind TDF's that Gilead did not obtain FDA authority to test TAF in humans until after Viread® was already on the market. (10App.3096, 3104.)

To continue developing TAF would have cost tens of millions of dollars, years of further study, and massive human resources. (7App.2313; 10App.3108-09, 3114-15.) That investment would have been wasted unless evidence showed TAF to have "significant benefits" over TDF *in humans*—i.e., to be materially superior to TDF—rather than "a mere replacement"

for TDF. (6App.1901, 1903; see 5App.1670.) Without such data, all those resources would be better devoted to developing the watershed single-tablet regimen built around TDF. Gilead's development team thus devised concrete, measurable "go/no go" criteria reflecting the requisite level of improvement. (6App.1901, 1903.)

To test TAF against these development criteria, Gilead designed a limited Phase I/Phase II trial, called "Study 1101"—the only source of data on TAF in humans in the relevant time frame. (7App.2285; 10App.3105.) Phase I trials are small and short, focusing mainly on evaluating how a drug works in the human body, side effects associated with increasing dosages, and preliminary efficacy. (21 C.F.R. § 312.21(a).) Phase II trials "aren't large enough to show whether the drug will be beneficial" but "provide researchers with additional safety data" and efficacy information that inform protocols for pivotal and large-scale Phase III trials. (FDA, Step 3: Clinical Research (2018), https://tinyurl.com/fda-iii; 21 C.F.R. § 312.21(b), (c).) For the most part, only Phase III trials can amass the evidence necessary to satisfy FDA that a treatment is sufficiently safe and effective to be approved. (See 21 C.F.R. § 312.21(c).) Phase III studies "provide most of the safety data" during clinical trials because they "are larger and longer in duration, [and] the results are more likely to show long-term or rare side effects." (FDA, Step 3, *supra*.)

Consistent with Phase I and II goals, the limited Phase I/II clinical study of TAF was very small and short. (7App.2280-301.)

It entailed administering TAF to 20 patients and TDF to 10 patients, for a mere 14 days. (7App.2287, 2296.) Its purpose was to provide "preliminary evaluation of both the antiviral potency and viral dynamics of [TAF] compared with [TDF]." (7App.2293.)

Study 1101 was completed in February 2003. Like the earlier preclinical results, Study 1101's results were mixed. Although the study showed "increase[d] … distribution" of TAF in targeted cells (7App.2301), its bottom line was that TAF failed to meet Gilead's pre-set criteria to be materially more effective than TDF (6App.1901, 1903 [defining benchmarks]; 7App.2289 [reporting efficacy results]).

Critically, the study found that TAF "showed safety profiles *similar* to that of [TDF]"—not, as Plaintiffs assert, that TAF was safer. (7App.2301 [study results], italics added.) Meanwhile, other data emerged suggesting that TAF might cause different side effects. A long-term nine-month toxicology study in dogs showed that TAF might cause cardiovascular and thyroid effects not associated with TDF. (7App.2304, 2321.) These results raised questions about TAF's "potential for long term safety," particularly at high doses. (7App.2304-05.)

Based on this divergent scientific evidence, Gilead decided to stop TAF development in 2004. Although there were "[p]oints in favor of continuing development," "[a] number of [Development Committee] members expressed the opinion" that TAF's "emerging profile ... does not appear to be sufficiently differentiated from Viread." (7App.2321.) In their view, TAF's "distribution profile" made "*predictability of safety impossible*."

(*Ibid.*, italics added.) Dr. Norbert Bishofberger, Gilead's Senior Vice President of Research and Development, made the final decision. (2App.462.) In so doing, he relied on the science—most notably, years of data in the real world from tens of thousands of people that had proved TDF to be safe, effective, and well-tolerated, while Study 1101 had not shown TAF to be safer or meaningfully more effective than TDF. (*Ibid.*)

Gilead Restarts TAF Development, Spending Tens Of Millions Of Dollars To Further Investigate TAF

Having achieved the TDF-based single-tablet watershed that benefited millions of patients, in 2010, Gilead turned its attention to a new problem—one arising from TDF's extraordinary effectiveness. 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. (8App.2653; 9App.2832.)

TAF was a logical option to explore on the chance that it might prove to be a lower-dose alternative for that aging population. (9App.2832-33, 2928-29; 10App.3108.) But Gilead's contemporaneous internal deliberations expressed continued uncertainty that TAF was any safer than TDF: Researchers considered it a "[h]igh" "[p]robability," "Major Risk[]" that TAF's "safety profile" "may not be different from that of TDF." (8App.2566, 2604.) They also continued to harbor concerns that TAF might be less safe than TDF. (8App.2574; *ante* 13, 15.) Only Phase III studies and large-scale head-to-head testing could allay those concerns.

In 2011, Gilead started its first Phase III study of TAF. For reasons described above, only 25-30% of drug candidates entering Phase III trials receive FDA approval. (*Ante* 13; see FDA, Step 3, *supra*.) TAF was in that minority. After more than four years of additional clinical research (including multiple head-to-head studies with TDF) and at least $82 million, Gilead obtained FDA approval for the first TAF medicine. (1App.152-53; 7App.2313; 8App.2583.)

Plaintiffs Assert A Novel Negligence Claim Based On A Duty To Promptly Bring A New Product To Market

Thousands of Plaintiffs sued Gilead claiming to have suffered the bone and kidney side effects disclosed on TDF's label. Plaintiffs do not allege TDF is ineffective—indeed, many are alive today because of TDF. And Plaintiffs "do not seek to prove that TDF-containing medications are defective." (Op. 7; accord Op. 2, 12.) That means Plaintiffs do not contest that TDF is reasonably safe—that its benefits outweigh its risks. (COA.Arg.Tr. 41.) To the contrary, Plaintiffs concede that "TDF … ha[s] greatly helped patients with HIV" (*ibid.*), and "for a variety of reasons, some physicians and patients prefer TDF over TAF." (Pls.' Suppl. COA Br. 22.) Plaintiffs also do not dispute the adequacy of TDF's warnings. (1App.99-100.)

Instead, Plaintiffs assert an unprecedented duty: that Gilead should have brought TAF to market earlier to give them an alternative choice to TDF. Plaintiffs agree that when FDA approved the first TDF medicine, "TAF was not a safer alternative yet" because "[i]t was still in development."

(COA.Arg.Tr. 43.) Nevertheless, Plaintiffs claim that everything changed once Gilead obtained the data from the 14-day, 30-person Study 1101. Based on that study, Plaintiffs claim that, in 2004, Gilead "knew, or should have known, … that TAF [wa]s safer than TDF." (1App.69.) They argue that Gilead therefore had a duty "to commercialize a TAF-based medication." (Op. 7.) They take this position even though Study 1101 concluded that TDF and TAF had "similar" safety profiles and two of Plaintiffs' own experts concede that Gilead did not know that TAF was safer than TDF in 2004. (7App.2301; 2App.443-46; 2App.410-12, 414-15.)

Central to Plaintiffs' claim is an allegation of Gilead's motive for the delay. They allege that Gilead delayed a safer TAF in 2004 so it could "extend its patent protection" (Pls.' Supp. Reply COA Br. 43) on tenofovir medicines and make more money in a window of time at least 13 years later (2017-2021), between the then-forecasted expiration of TDF and TAF patents. (10App.3015-16; Ret. 14-16.) But the undisputed record belies that allegation.

Gilead laid out two alternative paths based on how TAF performed in humans. Gilead would follow Path 1 if TAF met the criteria demonstrating a meaningful improvement over TDF. (6App.1901; 7App.2314.) If so, Gilead would go all-in on TAF, proceeding with a full development strategy. Gilead estimated an *improved* medicine could yield an extra $1 billion over expected TDF revenues between 2008 and 2013. (7App.2314-15.) Gilead would then purposely "cannibalize" TDF's market share—i.e.,

shift TDF's entire patient population to TAF—and bring in additional revenue by expanding to new patients. (6App.1901, 1922.)

Path 2 was if TAF turned out *not* to be superior to TDF. (See 7App.2202-04.) In that scenario, there would be no reason to rush TAF to market; it would only "cannibalize Viread" (7App.2153) *without* helping current patients or attracting new ones. In that scenario—where TAF was *not* superior—Gilead could try to take advantage of possibly later-expiring TAF patents by shifting TDF patients to TAF after generic versions of TDF medicines became available. (*Ibid.*; 7App.2276.) In contrast to the billion dollars of extra revenue Gilead projected between 2008 and 2013 under Path 1 (7App.2314-15), Gilead would see no added revenue from TAF under Path 2 during that period, just the possibility of much smaller additional revenues at least 13 years later for the brief period of time between the TDF and TAF patents' then-anticipated expirations. (7App.2205, 2209; 7App.2153.)

Not a single document shows that Gilead ever considered delaying TAF development if data showed TAF to be a meaningful improvement over TDF.

The Courts Below Allow Plaintiffs' Negligence Claim To Proceed

Gilead moved for summary judgment on issues common to all Plaintiffs' cases. (1App.109-44.) As relevant here, Gilead argued that it had no duty to develop and market TAF earlier.

(1App.131-34.) The Superior Court denied Gilead's motion. (10App.3246.)

Gilead petitioned for a writ of mandate. The Court of Appeal granted the writ as to some claims, but allowed Plaintiffs' negligence claim to proceed. (Op. 3-4.) The court rejected the central tenet of products-liability law—that a manufacturer satisfies its duty to consumers by marketing reasonably safe, defect-free products. (Op. 12-34.) It held that a manufacturer's duty "to exercise reasonable care can … extend beyond the duty not to market a defective product" (Op. 3), reasoning that Civil Code § 1714 supplies a broader duty of care (Op. 9, 34). The court then determined that no "exception" to this broader duty of care is warranted under the factors enumerated in *Rowland v. Christian* (1968) 69 Cal.2d 108. (Op. 3, 34-59.)

In determining that no exception from the duty was warranted, the court limited its analysis to where a manufacturer "knows [a new product] is a safer, and at least equally effective, alternative" to the existing non-defective product. (Op. 11; see Op. 39-40, 47.) The court drew the "actual knowledge" predicate from Plaintiffs' allegations, not from proof in the summary-judgment record, as required. (See *Parker v. Twentieth Century-Fox Film Corp.* (1970) 3 Cal.3d 176, 181.) The court acknowledged that Plaintiffs' complaint alleges "that Gilead knew '*or should have known*' that TAF was safer than TDF." (Op. 11 & fn.5, italics added.) But it took "no position on whether plaintiffs should be permitted to include a constructive knowledge theory on remand," though the court observed that

constructive knowledge would require "a different *Rowland* analysis" and would present greater "challeng[es]" on several factors. (*Ibid.*; Op. 40.)

Gilead proposed two possible exceptions. The broader exception was that the manufacturer of a non-defective product does not owe its users a duty to develop and commercialize an alternative product. (Op. 39.) The court rejected this exception, but, again, only as it relates to the sliver of Plaintiffs' claim alleging Gilead *knew* TAF was safer than TDF. The narrower exception Gilead proposed was that a drug manufacturer cannot possibly owe a duty this early in the product-development cycle. (Op. 54 & n.19.) The court found that "such an exception could be warranted," recognizing that "commercialization" decisions made before "Phase III trials are completed" are "more complicated and challenging for a jury to evaluate" and "more susceptible to hindsight bias." (Op. 57.) Despite ample, undisputed evidence in the record regarding the necessity of Phase III trials, however, the court said it lacked a sufficient "factual record" to decide "whether it is appropriate to recognize" the proposed exception. (Op. 58.) The court remanded for further record development and dispositive motions, including on the narrower exception. (Op. 58-59; Reh'g Dec. 1-2.)

STANDARD OF REVIEW

This appeal revolves entirely around the scope of a manufacturer's duty. That is a question of law reviewed de novo, without deference to the Court of Appeal's assessment—including its weighing of factors for and against duty. (*T.H. v. Novartis*

Pharmaceuticals Corp. (2017) 4 Cal.5th 145, 163; see, e.g., *Vasilenko v. Grace Family Church* (2017) 3 Cal.5th 1077, 1098 [reversing after independent review of factors].)

ARGUMENT

Despite years of discovery, Plaintiffs have no claim under any of the common-law duties that traditionally govern manufacturers. Plaintiffs have "abandon[ed] any attempt to prove that TDF is defective." (Op. 12.) And they have withdrawn any argument that TDF's warnings were inadequate. (1App.99-100.) Those failures of proof are why Plaintiffs need this Court to impose an unprecedented duty on manufacturers.

In allowing Plaintiffs to proceed, the Court of Appeal committed two legal mistakes, each an independent basis for reversal. The court started with the threshold determination that a manufacturer could have *some* duty beyond producing a non-defective product, and that a consumer who claims injury from a manufacturer's product therefore does not need to prove that the product is defective. The court erred in abandoning the age-old and universal common-law rule requiring proof of a defect. And because Plaintiffs do not argue that TDF medicines are defective, summary judgment is required on that basis alone. (§ I.) Second, regardless of whether a manufacturer might have some additional duty beyond providing a non-defective product, the court erred in adopting the particular duty it fashioned: the duty to continue developing and commercialize an alternative product that is safer for some consumers—and to do so on a specified timeline. The disastrous consequences of that duty vastly

outweigh any purported benefits. And again, without that duty, Gilead is entitled to summary judgment. (§ II.)

I. This Court Should Not Abolish The Age-Old And Universal Rule That A Consumer Claiming Injury From A Product Must Prove A Defect.

The defect requirement is a critical and long-standing limitation on liability that serves both the goals of negligence law and the public interest. (§ I.A.) This Court's precedents do not justify abolishing the requirement. (§ I.B.)

A. The defect requirement is a critical and central limitation on liability.

1. Ask any manufacturer in any state what duties it owes to consumers of its product. They will say: "Sell the product without defects in design, manufacture, or labeling." (See *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1057 [explaining "three types of product defects"].) They will know that this means the product must be reasonably safe and accompanied by warnings of known risks. (See 50A Cal.Jur.3d Products Liability, § 1.) Full stop.

This is not a light burden. Juries across the country have held manufacturers accountable for failing to meet one or another of these duties. But when a manufacturer has satisfied all these duties—which Plaintiffs do not contest here—this standard protects the manufacturer from liability for injuries caused by its product. Obviously, manufacturers have other duties as well. They cannot, for example, lie about their products or defraud their customers. But a person who sues a manufacturer claiming

to have been *physically injured* by its product must prove one of these classic products-liability defects.

This Court has repeatedly assured manufacturers that satisfying those duties protects them from liability. It has declared that manufacturers "are liable in tort *only* when 'defects' in their products cause injury." (*Soule v. General Motors Corp.* (1994) 8 Cal.4th 548, 568, fn.5, italics added.) It has pronounced that "to recover from a manufacturer, a plaintiff *must* prove that a defect caused injury." (*Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 479, italics added.) It has explained that "[t]he duty of a manufacturer" in negligence is not to "design his product … to make it … accident-proof," but to use "reasonable care" to ensure that it is reasonably safe for its intended use. (*Pike v. Frank G. Hough Co.* (1970) 2 Cal.3d 465, 470.) This Court has developed a whole body of law aptly called Products Liability, because it governs "'the liability of those who supply goods or products.'" (*Merrill*, *supra*, at 478.) And it has defined that to mean liability "'for losses … resulting from so-called *defects* in those products.'" (*Ibid.*, italics added.) As even the Court of Appeal acknowledged, "no California case" has ever expressly decided that the law "permit[s] recovery even when there is no showing that the injury resulted from a product defect." (Op. 17.)

California is in good company: The defect requirement is the law everywhere. "[I]n *every other state*, whether a suit is based upon negligence or implied warranty, [courts] require the plaintiff to prove that the product itself is actionable—that something is wrong with it that makes it dangerous …. This idea

of 'something wrong' is usually expressed by the adjective 'defective' and the plaintiff must, *in every case*, in *every jurisdiction*, show that the product was defective." (*Prentis v. Yale Mfg. Co.* (Mich. 1984) 365 N.W.2d 176, 181-82, first italics added; accord *Slisze v. Stanley-Bostitch* (Utah 1999) 979 P.2d 317, 320.)[2]

2. The origins of the defect requirement confirm that it has always served an important role in suits against manufacturers for injuries from their products, whether couched in negligence or strict liability.

Until the 1930s, manufacturers had very limited liability for injuries caused by their products. Consumers who bought directly from the manufacturer had contract claims. (*Kalash v. Los Angeles Ladder Co.* (1934) 1 Cal.2d 229, 231.) But "the common law … thr[ew] 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." (*Ibid.*)

In eventually authorizing tort liability against manufacturers, this Court was clear that this was a limited "exception" to "the general rule exonerating manufacturers from third party claims." (*Beacon Residential Cmty. Assn. v. Skidmore, Owings & Merrill LLP* (2014) 59 Cal.4th 568, 574.) The Court did

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[2] The Court of Appeal suggested Idaho may be an outlier based on an old Ninth Circuit decision. (Op. 17 fn.9, citing *Toner v. Lederle Laboratories* (9th Cir. 1987) 828 F.2d 510.) But the Idaho Supreme Court has since clarified that "a plaintiff who brings a cause of action based on warranty, negligence, or strict products liability, has the *burden of proving a defect*." (*Hoopes v. Deere & Co.* (Idaho 1990) 788 P.2d 201, 206, italics added.)

not impose on manufacturers a general duty to act "reasonably" with respect to any decision that might affect a consumer, whether under § 1714 or otherwise. Rather, the exception was far more specific, with a crucial caveat: A plaintiff could recover in negligence only where a product "became, because of *defective* construction or assembling, an instrument imminently dangerous to human life or limb." (*Kalash*, *supra,* 1 Cal.2d at 233, italics added; see also *Beacon*, *supra*, 59 Cal.4th at 574 ["defective … elevators," "defective … tires," "defective railing"].) While these negligence decisions often mentioned the manufacturer's conduct in making the product, consumers were always required to prove that conduct resulted in *something wrong* with a product—a defect. Simply put, the defect requirement was born as a crucial limitation on *negligence* liability.

With strict liability, this Court further relaxed the requirements for tort claims against manufacturers, eliminating the negligence requirement while preserving the defect requirement. The result was that *both* actions required a defect: To recover in strict liability, a plaintiff "must prove that he was injured by a defect in the product …; whereas to recover in negligence the plaintiff must [also] prove … that the defect in the product was due to negligence of the defendant." (*Jiminez v. Sears, Roebuck & Co.* (1971) 4 Cal.3d 379, 383.)

This Court has since emphasized that a plaintiff cannot evade these established products-liability requirements by declaring, as Plaintiffs do here, that their complaint is not about the product, but about the defendant's conduct. (See *Merrill*,

supra, 26 Cal.4th at 480 [holding that plaintiffs could not "rely on 'negligent conduct'" to avoid products-liability requirements].) As this Court held in *Merrill*, it is wrong to "assume that an action [against a manufacturer for injury from a product] based on negligence is necessarily not a products liability action" subject to the requirement of proving a defect. (*Id.* at 483.)

This evolution refutes the Court of Appeal's suggestion that the sole "purpose of requiring proof of a defect is to prevent strict liability from expanding into absolute liability." (Op. 14.) The defect requirement was a critical element of *negligence* suits against manufacturers—before the advent of strict liability. This history also explains why the court was wrong to abandon the defect requirement on the ground that the adoption of strict liability "did not purport to displace negligence as a cause of action." (Op. 15.) No one is saying strict liability displaced negligence. The point is that the negligence claim *itself* always required a consumer claiming injury from a product to prove a defect. Strict liability did not *add* that requirement, but rather *inherited* it.

3. This Court should not break from this established, widespread rule, because the defect requirement continues to serve important goals. To start, this straightforward rule "provides a clear and simple test for determining whether the injured plaintiff is entitled to recovery." (*Cronin v. J.B.E. Olson Corp.* (1972) 8 Cal.3d 121, 135.) The "ultimate question"—whether the product's risks outweigh its benefits—is easy to understand, focused on concrete considerations, and reasonably

bounded. (*Kim v. Toyota Motor Corp.* (2018) 6 Cal.5th 21, 35, 37.) Decades of caselaw guide courts and juries in defining "defect." All that clarity and guidance is squandered the moment the defect requirement is abolished. Without that requirement, there is no limit to the business decisions that a plaintiff can challenge. Plaintiffs here challenge a complex business decision to stop developing a new product—or not to market it quickly enough. That, alone, is an expansive duty with profound ramifications. (*Post* 33-60.) But under the Court of Appeal's logic, once the duty of reasonable care moves beyond the product the consumer used to other business decisions, the duty becomes endless, with different classes of plaintiffs created by each corporate decision. The next plaintiff can challenge a corporate decision to distribute that other product through hard-to-access channels. Or not promote it enough. Or to price it beyond the means of the injured consumer. Or to continue to sell the original (non-defective) product. Some other plaintiff could challenge a company's decision not to even start investigating in the first place. Or a corporate decision not to alert its consumers to another manufacturer's safer product. Each of those plaintiffs will be able to trace a causal chain from that corporate decision and declare the resulting injury foreseeable. The strands and permutations of liability are paralyzing.

Relatedly, the defect requirement ensures that a manufacturer will be held liable only for "injuries proximately caused by any of its products which are adjudged 'defective.'" (*Cronin*, *supra*, 8 Cal.3d at 133-34.) The further a plaintiff strays

from challenging the qualities of the injurious product, the more attenuated causation and foreseeability become.

The defect requirement also achieves the key goal of negligence law: to strike a balance between safety and access. It ensures that products are reasonably safe for consumers, while also ensuring that products do not become impractical, unavailable, or prohibitively expensive. (See, e.g., Perry, *Harmful Precautions* (2023) 99 Notre Dame L. Rev. 153, 180-81 [observing that tort law weighs the "negative externalities" of a defendant taking precautions, including the impact on a product's "availability and affordability"].)

The first half of that balance is critical: Products-liability law already protects consumers from unsafe products. (*Ante* 23-24.) The safety of other designs is highly relevant under this common-law analysis, because the "feasibility of a safer alternative design" is built into the definition of "defect." (*Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413, 431.) Courts and juries consider the "mechanical feasibility" and "financial cost" of an alternate design and "the adverse consequences … to the consumer that would result from an alternative design." (*Ibid.*) Thus, the common law already takes account of whether there is a safer way to make a product. The "explicit[] focus[]," however, is always "on the adequacy of the [existing] product itself" and whether it is unreasonably unsafe (i.e., defective). (*Id.* at 432.)

Throughout this litigation, Plaintiffs have offered no evidence, and no reason to believe, that traditional products-liability law is failing to protect consumers adequately. That is

because the defect requirement has protected consumers by requiring manufacturers to sell reasonably safe products and educate consumers about product risks. Every additional business decision that subjects a manufacturer to liability skews the balance and forces the manufacturer to make different decisions that will limit consumer choice. After all, the point of imposing a "duty" is to communicate "the fact that the actor is required to conduct himself in a particular manner at the risk that if he does not do so he may become liable to another." (Rest.1st Torts, § 4.)

Nowhere is it more important to strike the right balance than in the pharmaceutical context. This Court has emphasized that, because prescription medications "save lives and reduce pain and suffering," "[p]ublic policy favors the development and marketing of beneficial new drugs, even though [they present] some risks, perhaps serious ones." (*Brown*, *supra*, 44 Cal.3d at 1063.) The Court pointed specifically to the danger that excessive liability could make manufacturers "reluctant to undertake research programs to develop" new medicines or drive "the cost of medication[s] beyond the reach of those who need [them] most." (*Ibid.*) Meanwhile, the need for regulation through the tort system is diminished because prescription medicines go through an "onerous" regulatory process that ensures the safety of a drug's design and the adequacy of its warnings. (*Mutual Pharmaceutical Co. v. Bartlett* (2013) 570 U.S. 472, 476.)

Finally, eliminating the defect requirement yields a doctrinal paradox. This Court has repeatedly recognized the

claim of negligent design defect. (E.g., *Jiminez*, *supra*, 4 Cal.3d at 383.) The claim requires a plaintiff to establish *both* a design defect *and* the manufacturer's negligence. (*Merrill, supra*, 26 Cal.4th at 479.) If a plaintiff injured by a product could establish a negligence claim against that manufacturer without proving a design defect, negligent design defect would be a dead letter: No plaintiff would undertake to prove the "additional element" of defect, if he can impose liability based on a manufacturer's conduct alone. (*Ibid.*) Neither Plaintiffs nor the Court of Appeal have explained why this Court would have wasted its time crafting an entire body of law defining a superfluous claim.

B. This Court's precedents do not support abolishing the defect requirement.

The Court of Appeal was mistaken in observing that "a variety of cases demonstrate … that a manufacturer's duty to injured customers can extend more broadly than the duty to make a non-defective product." (Op. 17.)

The main example was *Mexicali Rose v. Superior Court* (1992) 1 Cal.4th 617. The case has limited value because, as the court conceded, it "ar[ises] in [an] atypical context" where it "did not expressly consider … the need to prove a defect to recover for harm caused by a product." (Op. 19.) Plus, there *was* a defect. There, a restaurant patron choked on a bone that should not have been in his chicken enchilada. This Court held that the patron could sue for the restaurant's failure to exercise reasonable care in the preparation of the dish. (*Mexicali Rose*, *supra*, at 630.) That is a classic products-liability duty: to avoid a *manufacturing*

defect in which the preparation process "result[s] in a product that differs from the manufacturer's intended result." (*Brown*, *supra*, 44 Cal.3d at 1057.) Given that fact, *Mexicali Rose* does not even suggest that there is an independent negligence duty that overrides and extends beyond providing a non-defective product.

Likewise inapposite are the Court of Appeal decisions in *Lunghi v. Clark Equipment Co.* (1984) 153 Cal.App.3d 485 and *Hernandez v. Badger Construction Equipment Co.* (1984) 28 Cal.App.4th 1791. Those cases *did* implicate product defects—ones that developed after the sale, rather than before it. That is, the cases involve a manufacturer that inadequately retrofits or fails to recall a product that was not defective when sold but became "defect[ive]" over time. (See CACI No. 1223; *Hernandez*, *supra*, at 1826-28 [upholding jury finding of negligence for not adequately retrofitting the crane to cure a later-arising defect, "discovered after the machine had been on the market for a while"]; *Lunghi*, *supra*, at 494 [upholding verdict for failure "to conduct an adequate retrofit campaign" of a post-sale defect, italics omitted].) The Court of Appeal insisted the products in those cases were not defective. (Op. 21.) But that is precisely how courts have interpreted their holdings. (See, e.g., *Johnson & Johnson Talcum Powder Cases* (2019) 37 Cal.App.5th 292, 318 [interpreting *Hernandez* as "concern[ing] the manufacturers' alleged negligence in failing to correct a defect affecting an earlier model of a product still in use"].)

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In sum, this Court's repeated pronouncements that a plaintiff claiming injury from a product cannot recover from a manufacturer without proving a defect are grounded in history and sound policy. This Court should not override these considerations and defy settled expectations. (See *Sierra Club v. San Joaquin Local Agency Formation Com.* (1999) 21 Cal.4th 489, 504 ["'Certainty, predictability and stability in the law are the major objectives of the legal system; i.e., that parties should be able to regulate their conduct and enter into relationships with reasonable assurance of the governing rules of law.'"].) Because Plaintiffs do not assert that the TDF medicines are defective, their negligence claim cannot survive summary judgment.

II. The Specific Duty The Court Of Appeal Recognized Is Unwarranted, Unjustified, And Disastrous.

Apart from the threshold point that a manufacturer cannot be held liable for injuries caused by a non-defective product, this Court should reverse for a separate reason: The specific duty the Court of Appeal adopted will yield disastrous policy consequences that vastly outweigh any purported benefit.

The duty the Court of Appeal thrust on every manufacturer is to develop and commercialize an alternative product that it knows to be safer for some subset of consumers—and to do so without delay. That duty will so frequently provide a separate—and less demanding—means of imposing liability on manufacturers that it will displace the previous standard of care

and replace it with an unbounded standard where reasonably safe is no longer safe enough. (§ II.A.) The Court of Appeal failed to justify this departure from the common law, applying the wrong legal framework in determining whether to recognize this duty. (§ II.B.) Under any framing, the policy considerations weigh strongly against recognizing a duty that breaks so starkly from the common law. (§ II.C.) And, at a minimum, any duty to continue developing a purportedly safer alternative cannot attach this early in the drug development process. (§ II.D.)

A. This duty displaces the existing ordinary-care standard with a boundless rule.

1. Abandoning the defect requirement, alone, squanders many of the benefits courts worked to achieve: the clarity and ease of applying a standard guided by decades of jurisprudence, the standard's connection to proximate cause principles, the value of balancing safety and access, and the benefits in encouraging further research and innovation. (*Ante* 27-31.) The particular duty the Court of Appeal imposed does even further violence to the common law. Requiring manufacturers to develop and commercialize safer alternatives to existing, non-defective products fundamentally alters manufacturers' standard of care. Instead of focusing on the qualities of the product that is (and should be) on the market, the duty focuses on products that are not on the market. Whereas the common law would find it decisive that "the benefits" of the existing product "for hundreds of thousands" of consumers "vastly exceed[]" the product's risks, that is now "irrelevant." (Op. 32.) Instead of asking whether the

product on the market presents "'excessive preventable danger,'" *any* "'preventable danger'" will trigger liability. (Contra *Barker*, *supra*, 20 Cal.3d at 430.) So, contrary to this Court's direction, manufacturers will be held liable for failing to market the "safest possible" product—even when the product they actually sold is reasonably safe. (*Soule*, *supra*, 8 Cal.4th at 571, fn.8.)

This duty blows past several other liability limitations that the common law carefully developed. In contrast to products liability's focus on whether the product is reasonably safe across the range of consumers, this duty threatens liability whenever an alternative product would lower the risk of injury suffered by *this plaintiff*. (See Op. 42 [duty triggered by an alternative product that is "safer and at least equally effective for the patient concerned"].) Manufacturers can be liable even if the alternative is not safer overall; in this case, Plaintiffs had to concede that "for a variety of reasons … some physicians and patients prefer TDF over TAF." (Pls.' Supp. COA Br. 22; see also 3App.995 [noting different side effects associated with TAF].) Manufacturers also can be liable where the risk of injury is, as here, extremely low (*ante* 12), and when the existing product contains sufficient warnings (*ante* 12, 17). Similarly, the duty applies regardless of the costs associated with bringing the alternative product to market; in this case, years of clinical trials and $82 million. (1App.152-153; 7App2313; 8App.2583.)

If the Court of Appeal thought this duty could coexist alongside products-liability law, it was wrong. The duty provides a way to hold a manufacturer liable even when a plaintiff's claim

would otherwise fail because a manufacturer satisfied the existing standard of care. A plaintiff need only redirect attention from the condition of the allegedly injurious product itself to a manufacturer's "discrete conduct" with respect to a different product in development. (Op. 28.)

This new backdoor to liability will arise frequently—to the point where the standard products-liability action may well become obsolete. Manufacturers often have the knowledge necessary to develop and commercialize alternatives to their existing products that would avoid harms to *some* consumers. So this duty will come into play almost *any time* a consumer is injured:

- A carmaker, knowing that speed kills, could be liable for failing to include a feature that caps car speeds at the speed limit—even if its cars are reasonably safe, a car with that feature would fail in the marketplace, and the feature might introduce added risks.
- A maker of personal protective equipment could be liable for failing to dedicate its resources toward producing a full-face air purifying respirator, known to be marginally more protective, even if N-95 masks filter out the vast majority of potential infectants and are much more affordable.
- A manufacturer of IUDs could be liable for injuries arising from IUD-displacement, if it declined to develop an alternative less likely to shift over time but much more uncomfortable to the user.

- A carmaker could be liable for injuries caused by cars drifting from the road if plaintiffs can show that, with a shift in development priorities, known lane-assist technology could have been released sooner.
- A maker of cleaning products could be liable for failing to develop and commercialize versions of its products that omit certain known allergens, even if only a tiny subset of the population has those allergies.
- A phone manufacturer could be liable if it knew it could automatically disable texting while driving, even though the feature would be wildly unpopular.

As these examples illustrate, this duty can expose to liability just about every development decision any manufacturer makes in any industry.

2. This duty also conflicts with another common law limitation specific to the pharmaceutical context. In *Brown*, this Court rejected strict liability for prescription medicines. In doing so, the Court rejected a legal standard, called the *Kearl* test, that was remarkably similar to the duty the Court of Appeal adopted here. (See *Brown*, *supra*, 44 Cal.3d at 1066-67.) The test would have expanded a drug manufacturer's liability if an "'alternative … would have *as effectively* accomplished the *full intended purpose* of the [drug],'" because then the drug would not be considered "unavoidably unsafe." (*Id.* at 1066-68.)

Brown's rationale for rejecting *Kearl* is at war with the duty here. This Court said that the rule would "diminish[]" a "manufacturer's incentive to develop … a superior product,"

because "a trial court could decide, perhaps many years later, that in fact another product which was available on the market would have accomplished the same result." (*Id.* at 1068.) That is exactly what the Court of Appeal did here—except TAF was not "available," but years away from getting to market. *Brown* was also concerned that the inquiry into safer alternatives will be skewed: "the question of the superiority of one drug over another would have to be decided not in the abstract but in reference to the plaintiff," when the medicine that injured that plaintiff might in fact be safer, with significant benefits, for others. (*Ibid.*) That is also the problem here: A jury would be considering the balance Gilead (or any other manufacturer) struck from the perspective of an outlier patient who suffered the rare side effect—not from the perspective of the millions of people who benefited from the course Gilead took without experiencing that side effect. And it would result in the precise danger *Brown* feared: the risk that excessive liability could make manufacturers "reluctant to undertake research programs to develop" new medicines or could drive "the cost of medication[s] beyond the reach of those who need [them] most." (*Id.* at 1063.) The result would be fewer medicines that "save lives and reduce pain and suffering." (*Ibid.*)

B. The Court of Appeal applied the wrong legal framework.

1. The Court of Appeal never grappled with how its decision affected the finely calibrated common-law standard of care currently governing manufacturers' conduct. It never considered why this Court insisted on a defect requirement in

negligence claims, much less determined that this requirement no longer serves public welfare. The Court of Appeal avoided any such inquiry by assuming that Civil Code § 1714 supplements products-liability law with a free-floating duty of care for manufacturers regarding their development and commercialization of other products. That would mean that for 150 years, § 1714 has imposed this duty governing undeveloped and unmarketed products, even though no plaintiff ever sought to enforce it and no court ever applied it. That assumption left the court to ask only whether Gilead had justified carving out an exception to that supposedly already-existing duty, applying the factors set out in *Rowland, supra*, 69 Cal.2d 108. (Op. 34-37.)

That framework was wrong at every step. To start, § 1714 does not modify or supplement common law duties; it subsumes them. Section 1714 says: "Everyone 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." (Italics added.) "Ordinary care" in § 1714 means the degree of care typical in a given context—i.e., in the industry and under the circumstances presented. (See *Austin v. Riverside Portland Cement Co.* (1955) 44 Cal.2d 225, 232-33, 236.) The context here is a claim against a manufacturer for injuries caused by the manufacturer's product. (Op. 2.) In this context, the traditional duties that products-liability law imposes on manufacturers *are* the "ordinary care" that § 1714 requires. (*Ante* 23-27; see also *Milwaukee Electric Tool Corp. v. Superior Court* (1993) 15

Cal.App.4th 547, 551, 557 [manufacturer that satisfies these duties has not "'depart[ed] from [the] proper standards of care'"].)

That is so despite Plaintiffs' effort to reframe their claim as focused on Gilead's "discrete conduct" with respect to a completely different product. (Op. 28.) The Court of Appeal correctly called these "products liability actions" (Op. 26) and asserted that it is Gilead's decision to "sell[] TDF, a drug with harmful side effects" that "created the risk of harm" (Op. 36). Plaintiffs resist that by insisting that their claim is not based on "the design and marketing of TDF," but on the failure to develop and market TAF sooner. (Op. 28.) That reframing, however, violates another limitation on § 1714: Section 1714 distinguishes between "misfeasance and nonfeasance." (*Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 214.) It targets "active misconduct working positive injury to others," not "fail[ing] to take positive steps to benefit others" (*id.* at 214-15), like not developing a new product. Plaintiffs cannot have it both ways.

However the claim is framed, Plaintiffs cannot ignore existing limits on the reach of § 1714, which is certainly not a device for undoing the finely calibrated balance of obligations the common law has developed over the course of a century. This Court has explained that § 1714 reflects "the intention of the Legislature to announce and formulate existing common law principles," while allowing for "continuing judicial evolution." (*Li v. Yellow Cab Co.* (1975) 13 Cal.3d 804, 814.) So unless the Civil Code clearly indicates otherwise, § 1714 must be "construed in light of common-law decisions on the same subject." (*Id.* at 815.)

That means that, far from providing a means to evade or override the strictures of products-liability law, § 1714 "incorporat[es]" those "developments" into the relevant duty. (*Id.* at 822.)

That does not mean that courts never have the power to recognize new duties previously unknown to the common law. But it means that a court may not "establish[] a broad, expansive duty" without first "tak[ing] … account of the established authority recognizing reasonable limitations" on liability for the same actors engaging in the same conduct. (*Parsons v. Crown Disposal Co.* (1997) 15 Cal.4th 456, 461.) Before expanding an existing standard of care, the court must determine that the existing duty does not sufficiently protect the public from harm and should be overridden.

In *Parsons*, for example, this Court felt obliged to examine the history and rationale behind traditional limits on liability for a category of injuries before deciding whether to "increas[e] the burden" on defendants. (*Id.* at 465-74.) The case involved injuries caused by a horse that had been startled, and before even considering changing the duty, this Court assessed the "social utility" analysis that had driven the previous no-liability rules, as well as other "policy consideration[s]" motivating the previous caselaw. (*Id.* at 473-74.) Only after understanding the reasoning behind limitations from the "earl[ier] cases" can a court decide whether the "analysis has changed to direct a different result." (*Id.* at 473-74.) The Court of Appeal, however, conducted no such analysis. It was improper for the court to override the defect requirement—much less to adopt a new duty eviscerating

common-law standards—without concluding that some new social-utility calculus justified the departure.

Ignoring all these principles does violence not only to the common law but to common sense. It is absurd to suggest that the duty the Court of Appeal recognized has existed since 1872 and no one thought to invoke it. Section 1714 was enacted long before this Court first permitted downstream consumers to bring negligence claims against manufacturers, but this Court still imposed the defect requirement. (*Ante* 25-27.) Nevertheless, the Court of Appeal's approach treats the defect requirement as a nullity from inception because § 1714 is about reasonableness, not defects.

These principles also explain why the Court of Appeal was wrong to apply a "*Rowland* analysis" asking whether to carve out an exception from a duty established by § 1714. (Op. 37.) When the common law has already reached a considered policy judgment to impose a limit on liability in a particular context, that limitation is the law; the defendant is not required to justify it again under *Rowland*. Courts must instead treat that conduct as presumptively exempt from any duty under § 1714. (*Parsons*, *supra*, 15 Cal.4th at 478.) The burden is then on the *plaintiffs* to justify "expand[ing] the limited duty of care imposed by the common law." (*Ibid.*) Because Plaintiffs here seek to expand manufacturers' legal duty beyond existing common-law limits, Plaintiffs have the burden of justifying the expansion.

2. The Court of Appeal committed a second framing error in addressing the question of duty. The court limited its *Rowland*

analysis to a narrow band of circumstances where a manufacturer has "actual knowledge" that the alternative candidate is "safer" than the existing, non-defective product. (Op. 39-40; see Op. 11.) If knowledge were a limitation on this negligence claim, this would be an outlier in negligence law. But the court refused to say the duty is limited to that circumstance, welcoming Plaintiffs to assert constructive knowledge *in this case*, even while emphasizing that the analysis on key factors would be "different." (Op. 39-40; see Op. 11-12, fn.5.) That approach was legally wrong. This Court should decide the case before it—the whole case, not some gerrymandered piece of it.

"California law looks to the entire 'category of negligent conduct,'" not to a "narrowly defined set of circumstances." (See *Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 774.) This Court is free to impose the actual-knowledge "limitation on the scope of the duty" after analyzing all the considerations. (*Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1154-55.) But since negligence *includes* cases involving constructive knowledge, the Court should not simply decline to address a vast subset of the "'general class of cases'" implicated by Plaintiffs' theory. (*Cabral*, *supra*, at 773, fn. 3.) This artificial truncating of the duty analysis leaves manufacturers, litigants, and courts at sea on critical questions that will affect behavior. That is especially so under the Court of Appeal's framing, because the duty presumptively applies to constructive knowledge unless and until manufacturers prove an exception under *Rowland*.

Moreover, the decision to avoid ruling on constructive knowledge does not reflect the record in this case—or even properly track Plaintiffs' allegations. Plaintiffs' complaint explicitly invoked constructive knowledge, alleging Gilead "knew, or should have known, … that TAF is safer than TDF" (1App.69), and Plaintiffs *defended* that standard on appeal (Pls.' Supp. Reply COA Br. 21-22). True, Plaintiffs try to get rhetorical mileage out of building their *narrative* around the sensational accusation "that Gilead *knew* TAF was safer than TDF," to the point where "knowledge appears to be necessary to the motivation plaintiffs attribute to Gilead[]." (Op. 11-12, fn. 5; see Op. 39.) But constructive knowledge is still very much in the case. Before filing this brief, Gilead asked Plaintiffs whether they were prepared to disavow a theory based on constructive knowledge. Plaintiffs declined. Given the impossibility of proving actual knowledge on these facts, it seems highly unlikely that Plaintiffs will ever want to litigate this case without a constructive-knowledge option. (*Ante* 14-16; *post* 61-63.)

C. Policy considerations fall far short of justifying the duty under any framing.

Whether the inquiry is framed as recognizing a new duty (under *Parsons*) or carving out an exception from an existing duty (under *Rowland*), and whether or not the inquiry is limited to actual knowledge, policy considerations fall far short of justifying a duty that breaks so starkly from the common law. Under any rubric, the analysis of duty requires a "comprehensive look" at "'the sum total' of the policy considerations at play." (*S. Cal. Gas*

Leak Cases (2019) 7 Cal.5th 391, 399, 401.) That includes the factors already addressed, such as the adequacy of current duties in protecting consumers (*ante* 27-31); the importance of not disrupting settled expectations (*ante* 23-25, 27-28); and "doctrinal confusion" (*ante* 30-31, 34-39; see *S. Cal. Gas*, *supra*, at 410). It also includes legal uncertainties associated with the new rule and its workability. (*S. Cal. Gas*, *supra*, at 401-03, 410 [considering the danger of chilling "socially beneficial behavior[s]," "difficult line-drawing questions," and questions of "workab[ility]"]; see *Bily v. Arthur Young & Co.* (1992) 3 Cal.4th 370, 398-406; *Parsons*, *supra*, 15 Cal.4th at 476-77.) And, of course, it includes the range of foreseeability and public policy considerations enumerated in *Rowland* but also routinely considered in cases addressing whether to recognize a new duty. (See, e.g., *S. Cal. Gas*, *supra*, at 401-02.) We address these factors in turn.

Workability & unpredictability. The Court of Appeal replaced a standard of care that judges and juries can understand, through the benefit of a century of judicial explication, with one that raises countless legal questions and that is incapable of principled application. The court offered no guidance as to how a jury should evaluate the reasonableness of a manufacturer's decision *whether* or *when* to dedicate its finite resources toward the development and commercialization of a new product. This determination is much more complicated and multifaceted than the binary defect/no-defect determination.

Consider the numerous legal questions and line-drawing exercises the Court of Appeal's decision leaves in its wake:

- Does a manufacturer have the duty to develop an alternative product that would mitigate some safety risks while exacerbating others?
- May a manufacturer commit its resources to pursuing a product that would serve a greater consumer need, even if it means not ameliorating safety risks of an existing product?
- What degree of delay becomes unreasonable, and what if the manufacturer dedicated that time toward pursuing other helpful products?
- How does one assess the economic considerations of product-development decisions, including how far from approval a new product is and how much money, time, and human capital are necessary to complete development and get that new product approved?
- How much may a manufacturer consider profit before a jury could find that the manufacturer unreasonably favored profits over patients or consumers?
- The Court of Appeal emphasized that it was recognizing a duty only where the manufacturer has *already* "invented" a safer alternative (Op. 11), not a duty to "develop" one (Op. 10, fn. 3). Is there a duty to "develop" a product not yet "invented," and where exactly is that line?

Discarding a century of precedents condemns courts to spend the next century figuring all this out. (See *post* 55-56.)

Whatever the answers to these legal questions, juries will be rudderless in applying a standard that boils down to "make reasonable decisions." The trial court's *Sargon* decisions illustrate the challenge: It rejected expert testimony because the intricate "business decision[s]" at issue are "informed by medical *and* financial concepts" and there are no measurable standards against which to assess these choices, like "professional negligence" or "malpractice" or "compliance with standards for clinical trials, … FDA regulations, or *the safety of an assertedly defective product*." (10App.3275, italics added.) Without "measurable standards" or other guidance, juries will just make it up.

The Court of Appeal itself agreed that a duty to "'pursue *ever-better* new products or improvements to existing products' would be unworkable and unwarranted." (Op. 10.) Yet the duty it imposed is equally unworkable and unwarranted: The only difference is that the duty the court recognized entails proof that a manufacturer "knew" how to make a safer product (at least for now, until some court rejects that limit, in this case or some later case). As explained, manufacturers routinely have that knowledge (*ante* 36-37), and once they do, they will be obliged to either pursue the safer product or face massive, retrospective liability—with no meaningful limits or standards to judge the reasonableness of their choice and often no practical ability to make a product that is safe for all consumers.

These uncertainties will leave manufacturers guessing what is expected—and thus overcorrecting. (*Post* 51-53.)

Foreseeability of harm to the plaintiff & closeness of connection to defendant's conduct. These two factors are so closely related that they are best addressed together. Foreseeability assesses 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." (*Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1022, italics added.) And "where the injury suffered is connected only distantly and indirectly to the defendant's negligent act," injury is less foreseeable. (*Cabral*, *supra*, 51 Cal.4th at 779.)

The Court of Appeal held that where the manufacturer has actual knowledge that the new product "poses a lower risk" of certain injuries, then "it is foreseeable that the manufacturer's delay in commercializing the new [product] will cause some users to suffer injury they could have avoided." (Op. 41.) The question is not whether injury can be foreseen at all. On a "'clear judicial day[] … a court can foresee forever.'" (*Bily*, *supra*, 3 Cal.4th at 399.) The question is *how* foreseeable it is that the development decision will be responsible for the plaintiff's particular harms—and *how* direct and "proximate" the connection is. (*Kuciemba*, *supra*, 14 Cal.5th at 1024.)

Generally, a decision to stop developing an alternative product is remote from injuries caused by an existing, non-defective product. At the point at which a manufacturer makes that decision, the likelihood that the decision will cause any later injury (potentially, years or decades later) will depend on a string of contingencies:

1. Will the alternative product make it to market, which depends on many factors—including whether enhanced safety along one dimension is offset by other risks or practicalities?
2. Will another need emerge that is far more important? And if so, will the manufacturer have the resources to address that and the alternative here?
3. Would consumers use the alternative product, which is by no means assured, whether because an intermediary (like a doctor or insurer) often makes the decision or because consumers prefer the existing product?
4. Will the existing product even remain on the market, or be superseded by another (and therefore become incapable of injuring anyone)?
5. Will another manufacturer invent a product with a different safety profile that would avoid the injury and thereby obviate the need for another alternative?

The causal chain is too attenuated for the injury to be sufficiently foreseeable to impose liability.

The connection is even more attenuated where, as here, a regulatory framework mediates consumers' access. Foreseeability factors have to "'account[] for third party or other intervening conduct.'" (*Kuciemba*, *supra*, 14 Cal.5th at 1023.) A manufacturer can believe (or "know") that some new product is safer, but that does not translate into certainty that it will *actually* reach consumers and avoid existing harms. With an 88% failure rate for clinical trials, for example, FDA approval is especially

unpredictable. (Op. 43; FDA, Step 3, *supra*.) Many manufacturers are bullish on a drug candidate, including through Phase III trials, only to have their hopes dashed with an FDA denial.

As the Court of Appeal suggested (Op. 43), all the contingencies become even less foreseeable, and the causal chain more remote, when the duty encompasses constructive knowledge. The less information a manufacturer has about an alternative product, the less foreseeable it is that the new candidate would prevent injuries. Yet, it is all too easy to assert in hindsight that the manufacturer "should have known" a developmental product would have turned out to be safer.

For example, the trial court would have permitted Plaintiffs to reach a jury with the argument that Gilead "knew" or even "should have known" TAF was safer than, and equally effective as, TDF in 2004 based on a Phase I/II clinical study that was not only tiny but found *similar* safety profiles. (*Ante* 17-18.) Plaintiffs' wager that some jury somewhere might agree only confirms that juries, with years of hindsight bias, may "overestimate or exaggerate the predictability" of outcomes that were far less foreseeable in real time. (*Chavez v. City of Los Angeles* (2010) 47 Cal.4th 970, 986-87.)[3]

Policy of preventing future harm. Because recognizing a tort duty will "induce behavioral changes," this factor examines whether such changes will make the public "safer." (*Kuciemba*,

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[3] The next *Rowland* factor, the "[d]egree of certainty that the plaintiff suffered injury," is irrelevant here because it applies only where the alleged harm is "'intangible.'" (*Kesner*, *supra*, 1 Cal.5th at 1148.)

supra, 14 Cal.4th at 1026.) Recognizing a duty of care for particular conduct might prevent *some* foreseeable harms for a subset of individuals, but nevertheless reduce safety and public welfare *overall*. That is the case here.

a. This duty will induce several behavioral changes with "negative societal consequences" overall. (*Ibid*.) First, manufacturers will veto studies to avoid the risk of acquiring too much knowledge about the possibility of a safer alternative. That is because a little knowledge of a promising alternative—gained, perhaps, through preliminary studies of possible safety improvements—might expose a company to liability later. This duty gives new meaning to the adage, "A little knowledge is a dangerous thing." Ultimately, slowing research into safety improvements will slow the rate at which consumers receive new and improved products.

This effect is especially troubling in the pharmaceutical context: Precisely because so many drug candidates fail in clinical studies, it is standard practice to collect data on back-up candidates while proceeding with a lead candidate, as Gilead did with TAF. (See 5App.1675; Amgen Ltr. 5.) Declining to collect that data may insulate a manufacturer from liability—but it will also delay the development of beneficial medicines, especially if the lead candidate fails.

Second, once a business discovers a safer product, it will have to think twice about *ever* bringing it to market. Doing so automatically creates a new class of plaintiffs who can say that the alternative should have been released earlier, armed with the

company's own pronouncements about safety improvements. Unless the new product is especially profitable, the possibility of liability might be enough to sink it.

Third, this duty will improperly skew research priorities. The Court of Appeal was clear that a manufacturer can be subject to the duty only where it already has a product on the market that, while reasonably safe, has some side effects. (Op. 39.) To avoid liability, a manufacturer will have to prioritize addressing relatively minor side effects affecting small percentages of users. That would promote the interests of these potential plaintiffs over a potentially far greater societal interest in developing some new technological marvel for a population that will never be in a position to sue—for example, a historically neglected patient population for whom no treatment has yet been developed.

Overall, these behavioral changes will lead to the socially detrimental outcomes of less innovation, fewer alternative products, and abandonment of products consumers need the most.

The Court of Appeal dismissed these effects as "unsupported." (Op. 50.) But courts do not need testimony to support a bedrock principle of tort law: companies are incentivized to avoid liability. When researching improvements to existing non-defective products is *precisely* the conduct that will expose manufacturers to liability, for example, it is no leap to posit that such research will be chilled. Indeed, that is why, in the pharmaceutical context, this Court has expressly rejected liability rules that would enable plaintiffs to wield "advances in

scientific knowledge"—including the development of "superior product[s]"—against drug manufacturers. (*Brown*, *supra*, 44 Cal.3d at 1066, 1068; see also *ante* 30, 37-38.)

The Court of Appeal also failed to avoid the negative consequences by noting that the duty does not "require the pursuit of commercialization at all costs," but just targets *unreasonable* product-development decisions. (Op. 51.) That limitation offers scant comfort and no guidance to manufacturers when juries themselves have no useful guidance on how to assess whether a development decision was reasonable. (*Ante* 45-47.)

b. On the other side of the ledger, the Court of Appeal's duty will do little to further the goal of preventing other consumer harms, especially since existing law already ensures that existing products are reasonably safe. If the century old products-liability duties had proven inadequate, one would expect the Court of Appeal to be able to cite abundant evidence of the harms they have caused. But it cited none. It merely repeated Plaintiffs' "argu[ment] that recognizing a duty would result in speedier delivery" of the *choice* of an improved product. (Op. 49.) The court cited no evidence of that either, just Plaintiffs' further "argu[ment] that the patent system incentivizes drug manufacturers to" delay products "to extend their monopolies for as long as possible." (Op. 50.)

That is absurd. Tort law does not have to intervene to fix patent law (which itself has been in the background throughout the development of products-liability law). Manufacturers already have every incentive to rush improved products to

market because doing so will increase sales and profits in the near term. (Cf. *Vasilenko*, *supra,* 3 Cal.5th at 1088 [tort duty unnecessary because sufficient incentives already exist].) This is especially true in "[t]he pharmaceutical industry," which "is … highly competitive." (*Seife v. FDA* (2d Cir. 2022) 43 F.4th 231, 242.) Rational drugmakers release new medicines quickly because "the 'first mover' gains a considerable advantage." (*Kader v. Sarepta Therapeutics, Inc.* (1st Cir. 2018) 887 F.3d 48, 52.) This case is illustrative: If TAF had proven itself to be significantly better or safer than TDF in 2004, Gilead would have pursued full development of TAF, reaping $1 billion in additional revenue in the near term. (See 7App.2314; *ante* 18.) That would far surpass any uncertain and comparatively minimal benefits to be reaped from delaying TAF development in pursuit of extended patent protection 13 years later (and which in fact never materialized anyway). (*Ante* 19.)

The Court of Appeal twisted this economic imperative in favor of the duty, suggesting that if manufacturers are already incentivized to develop safer alternative products, this tort duty would not "radically alter" existing conduct. (Op. 51.) But those incentives are fostered by *current* rules with proper safeguards on the extent of liability; the court overlooked the ways in which its duty would distort manufacturers' future decision-making to the detriment of public welfare. (*Ante* 51-53.)

Burden on defendants and community at large. The harms to the community, in the form of innovation stifled and improved new products lost, were discussed above. Beyond that,

this unworkable duty will subject defendants to extensive liability and inundate them and the judiciary with time-consuming, complex litigation.

This Court has cautioned against a duty that "open[s] the courthouse doors to a deluge of lawsuits." (*Kuciemba*, *supra*, 14 Cal.5th at 1031; accord *Bily*, *supra*, 3 Cal.4th at 400.) This unprecedented duty would do exactly that because, as discussed, it is boundless. (*Ante* 34-37.) It covers any manufacturer. And it is owed to every consumer of the manufacturer's existing, non-defective product—a "potentially large class of persons," the Court of Appeal admitted. (Op. 53.) Such an "enormous pool of potential plaintiffs" weighs "forceful[ly]" against duty. (*Kesner*, *supra*, 1 Cal.5th at 1153; *Kuciemba, supra*, at 1030 ["litigation explosion" from inability to meaningfully limit potential plaintiffs weighs against duty].)

Worse, this duty threatens liability for just about any product-development decision. Every development path taken will give birth to a new class of plaintiffs for the path not taken. For example, had Gilead chosen to pursue TAF in 2004 rather than following FDA's plea to invest in the watershed single-tablet regimen, the millions of patients who benefited from that innovation could sue for delaying that safer alternative.

The burdens do not become tolerable just because the Court of Appeal thinks "plaintiffs would likely face a difficult road in establishing a breach of reasonable care." (Op. 52-53.) The number of trials a manufacturer might win is of limited value where, as here, "a very large number of suits" will be brought, all

"complex and time-consuming to litigate." (*Kuciemba*, *supra*, 14 Cal.5th at 1030.) And the right to have a jury decide whether a development decision was "reasonable" in the face of a sympathetic plaintiff with a lawyer railing about corporate greed is slim comfort, particularly where the standards are so nebulous and manipulable. (*Ante* 45-48.)

Here, for example, tens of thousands of individual Plaintiffs have litigated this case for five years. Yet their best evidence of knowledge is a 14-day early-stage clinical study announcing that TAF and TDF had a "similar safety" profile. If that is enough, it will always be possible to craft a "revisionist" narrative in which greedy executives ignored the best path. (*Bily*, *supra*, 3 Cal.4th at 401 [explaining the susceptibility to "plaintiffs' litigation-focused attention" might lead to liability disproportionate with fault].) The Court of Appeal was wrong to ignore the attendant burdens to the vast number of potential defendants, the judicial system, and ultimately the community at large.

Moral blame. Moral blame does not inherently attach to a manufacturer's decision not to pursue a potentially safer alternative to a non-defective product—or to pursue it, but just less expeditiously than a plaintiff would have liked. Every day, manufacturers of all sorts must make intricate, real-time product-development decisions that balance considerations of safety, practicality, consumer preference, price, and other development priorities. The scenarios discussed above—involving makers of cars, cleaning products, medical devices, protective equipment, and phones—illustrate the range and complexity of

development decisions that are not even arguably immoral. (*Ante* 36-37.) These manufacturers all *know* that the alternatives are safer for some subset of consumers, but they may choose not to devote finite resources to developing the safer alternative for a variety of legitimate, even compelling reasons, from unacceptable tradeoffs (as with the IUD that is less likely to shift but that causes more discomfort) to consumer preference (like the automatic speed cap) to prohibitive cost for the manufacturer and consumers alike (as in the powered air purifying respirator). And moral opprobrium is even less warranted when the manufacturer does not *know* an alternative is safer, but merely has information from which a detractor can assert that it should have known.

Assigning moral blame to such decisions is especially dissonant in the pharmaceutical context. This Court has repeatedly emphasized that socially beneficial conduct should not expose actors to liability. (See, e.g., *S. Cal. Gas*, *supra*, 7 Cal.5th at 402.) "[D]efendants' conduct"—developing lifesaving medicines—is "'of high social utility,'" which weighs against moral blameworthiness. (*O'Neil v. Crane* (2012) 53 Cal.4th 335, 365 & fn.13.) Drug-development decisions entail especially complex considerations that must account for finite resources, numerous possible research paths, and endless patient needs, all assessed with limited information in a highly regulated industry with even more unpredictable outcomes. Further mitigating any blame is the practical reality that a manufacturer declining to pursue one developmental path generally does so to pursue another, directing its finite resources toward other patient needs.

(*Ante* 12-14, 55-56.) It should thus rarely—if ever—be considered immoral to opt against dedicating immense financial and human resources toward improving upon an already reasonably safe medicine, when those same resources could instead be used, for example, to develop a treatment for a currently untreated disease.

Instead of addressing these complexities, the Court of Appeal treated the possibility of financial benefit as effectively dispositive on moral blame. (Op. 46.) But nothing about the duty the court recognized depends on proving financial benefit. Regardless, pharmaceutical companies must consider cost, because drug development is extremely expensive, costing on average a staggering $2.6 billion for each new medicine approved. (PhRMA COA Br. 21.) That unavoidable reality cannot be a basis for moral opprobrium.

Availability and cost of insurance. This factor, too, weighs against recognizing a duty. *Brown* explains that even if insurance were available, the "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." (44 Cal.3d at 1064.) Indeed, "the additional expense of insuring against such liability," if available at all, "could place the cost of medication beyond the reach of those who need it most." (*Id.* at 1063.) Worse, as *Brown* recounted, numerous pharmaceutical products have been withdrawn or withheld from the market because insurance was either prohibitively expensive or could not be obtained at all. (*Id.* at 1064-65.) And even if

insurance could be obtained at a manageable price, insurance has concrete limits—which a manufacturer can quickly exceed when facing widespread litigation. Again, this is "far from theoretical." (*Id.* at 1064.)

The Court of Appeal discounted this factor for lack of a record on "the cost and availability of insurance." (Op. 53.) But this Court's opinion in *Brown* already supplies all the necessary information. In any event, it is unclear what sort of record Gilead could have presented before any of these lawsuits ever went to trial. And even broadening the lens to all manufacturers, this factor is, at most, neutral. (See *Kuciemba*, 14 Cal.5th at 1030-31.) It certainly cannot outweigh the litany of other policy considerations counseling against recognition of this duty.

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On de novo review of the Court of Appeal's decision (*ante* 21-22), the balance of factors weighs decisively against recognizing the duty the court recognized, even with the actual-knowledge predicate, and more so when the duty is properly considered based on the facts and allegations here. The Court of Appeal was mistaken not only in its analysis of each relevant policy factor, but in the overall skew. The court placed undue emphasis on the conclusion that injury was foreseeable (Op. 53), repeatedly weighing it on almost every factor. (See, e.g., Op. 46 [morally blameworthy not to "'avert the foreseeable harm'"]; Op. 51 [weighing policy-of-preventing-future-harm factor assuming the alternative "would allow harm to be avoided"].) Meanwhile, the court undervalued the "burdens" of its duty, disposing of the

topic in just a page (Op. 52-53). It assumed the benefits of the duty it adopted without evidence or analysis, while dismissing the negative ramifications as "unsupported." (Op. 49-50.)

That was error. While the absence of foreseeability *alone* defeats the imposition of duty (*Dillon v. Legg* (1968) 68 Cal.2d 728, 739), foreseeability is not entitled to the weight the Court of Appeal assigned it. Even where there is a "legal certainty" that a category of conduct will lead to particular harms, this Court "will not" necessarily "recognize a duty of care." (*T.H.*, *supra*, 4 Cal.5th at 166, 168.) A sufficiently weighty "'burden on society'" can "'dictate a cause of action should not be sanctioned no matter how foreseeable the risk.'" (*Kuciemba*, *supra*, 14 Cal.5th at 1031.) Here, the "policy factors of preventing future harm and the anticipated burdens on defendants and the community weigh against imposing … a duty," regardless of the remaining factors. (*Ibid.*)

D. At a minimum, any duty to continue developing a purportedly safer alternative should not arise this early in the drug development cycle.

The narrowest way to resolve this appeal is to rule that there is no duty for the class of cases that arise this early in the drug-development cycle. Gilead had not even started Phase III studies when this duty purportedly attached. But a drug manufacturer cannot generally know that a candidate is safer than, and as effective as, an existing, approved drug before Phase III studies and head-to-head clinical comparisons.

The following facts—all undisputed or indisputable—justify such a ruling:

- Seven out of eight drug candidates (88%) that start clinical trials fail. (Op. 43.)
- 70-75% of drug candidates that start Phase III trials fail. (FDA, Step 3, *supra*.)
- Developing one drug costs, on average, $2.6 billion and takes 10 to 15 years. (PhRMA COA Br. 21.)
- By regulation, it is Phase III studies that provide "the overall benefit-risk relationship of the drug" (21 C.F.R. §§ 312.21(a)-(c)), and "most of the safety data" needed for approval. (FDA, Step 3, *supra*.)
- FDA approval (based on Phase III studies) and head-to-head clinical comparisons are so essential to establish comparative safety and effectiveness that it is generally *illegal* for a drug manufacturer to advertise that a medicine is "better, more effective," or "safer" than another drug without securing that data. (21 U.S.C. §§ 331, 352; 21 C.F.R. § 202.1(e)(6)(i)-(ii), (xvi).)

It is no surprise, then, that Plaintiffs' experts could not opine "that TAF was known to be safer than TDF in 2004"—asserting that "TAF showed promise," but "not that anything was known." (2App.443-46.) Indeed, Plaintiffs' experts concluded that Gilead lacked substantial evidence demonstrating TAF's and TDF's relative safety and effectiveness in 2004, opining that that would require, at minimum, Phase III and head-to-head studies. (2App.410-12, 417-18, 443-46.)

That is generally true of drug development across the range of diseases, ailments, and technologies. The duty the Court of

Appeal adopted applies where the drug manufacturer "knows [the new product] is a safer, and at least equally effective, alternative to a prescription drug that it is currently selling." (Op. 11.) It is generally impossible to *know* that without large-scale, longer-term Phase III clinical studies and head-to-head comparisons.

Just as a matter of common sense, administering a medicine for 14 days, as the 1101 Study did here, does not provide any assurance about safety over a lifetime. Likewise, bearing in mind that TDF's side effects impact one in 1000 or two in 100,000 patients (7App.2355, 2358-60), administering a new drug candidate to 20 subjects does not begin to provide the confidence necessary to know a candidate diminishes one category of side effects—or does not cause different, potentially more severe, side effects. FDA has specifically cautioned that before Phase III, "it is possible that less common side effects might have gone undetected." (FDA, Step 3, *supra* [Phase III "results are more likely to show long-term or rare side effects"].) The duty here also depends on equal effectiveness—which also cannot be known with any confidence based on small Phase I and II studies. That is why FDA approval requires Phase III studies (at minimum) in all but the most exceptional and dire cases.

The limits on what a drug manufacturer can know before completion of Phase III studies affects just about every one of the foreseeability and public policy factors, for reasons already discussed. If a manufacturer generally cannot know that a drug candidate is safer and equally effective without additional side

effects, then it is far less foreseeable that the candidate would prevent patient injuries, and the link between the manufacturer's decision to discontinue an investigation and the injury is even more attenuated.

Likewise, any such decision is far less likely to be morally blameworthy when a manufacturer cannot know that the alternative it is declining to continue studying is safer than the existing, reasonably safe medicine. It would be downright paradoxical to ascribe moral blame to a decision to discontinue investing in a potentially safer drug candidate when it would be illegal to even *say* that the medicine is safer.

Similarly, the earlier in the development trajectory that the duty attaches, the more severe the costs to society (in lost drug candidates and innovation) and the burdens on manufacturers and the community. The universe of drug candidates that could be affected by—and potentially lost because of—this duty is vastly higher if the duty extends into earlier phases. *Every* compound that shows initial promise could lead to litigation down the line if a drug company decides not to pursue it. That, in turn, would flout this Court's caution against liability rules that would enable plaintiffs to wield "advances in scientific knowledge" as weapons against drug manufacturers and undermine the interest in "incentiv[izing] [manufacturers] to develop … superior product[s]." (*Brown*, *supra*, 44 Cal. 3d at 1064, 1068.)

All of this is why the Court of Appeal acknowledged that "commercialization" decisions made before "Phase III trials are completed" are "more complicated and challenging for a jury to

evaluate" and "more susceptible to hindsight bias." (Op. 57.) But the court refused to consider limiting any duty on that basis. It said that it lacked the record to make "generalizations" about "what can reasonably be known after Phase II trials as compared to Phase III trials." (Op. 56.)

But this Court can decide the issue based on the undisputed facts, figures, and regulations recited above. Gilead and its amici have recited them all many times throughout this litigation. Plaintiffs have never disputed any of them, refuted their relevance, or challenged the inferences drawn from them—which, as discussed, their experts confirmed. (*Ante* 18, 61-62; see generally Pls.' Supp. Reply COA Br. 34-36.) In particular, the Court of Appeal worried that it did not have the record to conclude "how often … a drug's apparent promise after Phase II is undermined by unexpected results in Phase III." (Op. 56.) FDA has answered the question—70-75% of the time. (FDA, Step 3, *supra*.) Plaintiffs have never disagreed or suggested there is another way to view that number. There is no world in which they prove that statistic to be so inaccurate as to fundamentally change the duty calculus.

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For all these reasons, this Court should reject the negligence duty the Court of Appeal recognized. In the absence of such a duty, Plaintiffs' claim cannot survive summary judgment.

CONCLUSION

This Court should reverse.

July 15, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 8.204(c)(1) of the California Rules of Court, the foregoing is proportionally spaced and contains 13,981 words, according to the word processing program used to prepare it.

Dated: July 15, 2024

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I am a citizen of the United States, over eighteen years old, and not a party to this action. My place of employment and business address is Orrick, Herrington & Sutcliffe LLP, 51 West 52nd Street, New York, NY 10019.

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Executed on July 15, 2024 at New York, New York

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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

7/15/2024

Date

/s/Amy Gerrish

Signature

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