No. S283862

IN THE SUPREME COURT OF
THE STATE OF CALIFORNIA

GILEAD TENOFOVIR CASES

AFTER A DECISION BY THE COURT OF APPEAL, FIRST
APPELLATE DISTRICT, DIVISION FOUR, CASE NO. A165558

APPLICATION FOR PERMISSION TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF PETITIONER GILEAD SCIENCES, INC.; PROPOSED AMICUS CURIAE BRIEF

**AMICUS CURIAE BRIEF OF
PACIFIC RESEARCH INSTITUTE**

PACIFIC RESEARCH INSTITUTE

RICHARD A. EPSTEIN (43329)
raepstein43@gmail.com
16 Thomas Place
Norwalk, CT 06853
Attorney for Amicus Curiae Pacific Research Institute

APPLICATION TO FILE BRIEF

Pursuant to Rule 8.520(f) of the California Rules of Court, proposed *Amicus Curiae,* Pacific Research Institute ("PRI"), respectfully requests leave to file the attached brief of Amicus Curiae in support of Petitioners Gilead Sciences. Pursuant to Rule 8.520(f)(5) of the California Rules of Court, the proposed *amicus curiae* brief is combined with this Application. This application is timely made within thirty (30) days after the filing of the reply brief on the merits pursuant to Rule of Courts 8.520(f)(2). Accordingly, under Rule 8.520(f)(4)(A) and (B), only the attorney listed on the caption page of this Application drafted the accompanying brief.

IDENTITY AND INTEREST IN AMICUS CURIAE

Since its founding in 1979, PRI has remained steadfast to the vision of a free and civil society where individuals can achieve their full potential. Put simply, public policy is too important to be left just to the experts. Individuals are the real decision makers when it comes to their schools, health care, and environment. PRI reinforces this ideal by providing the public with the information, inspiration, and opportunity to make decisions about the daily issues that matter most. The Institute's activities include publications, events, media commentary, legislative testimony, and community outreach.

In the attached brief, PRI presents a detailed analysis of the flaws in the lower court's poorly articulated arguments regarding a pharmaceutical company's potential liability for its decision on drug development timelines.

No party, counsel for a party, or any person other than counsel of the amicus authored the proposed amicus in whole or in part or made a monetary contribution intended to fund the preparation or submission of the brief. (Cal. Rules of Court, rule 8.520(f)(3)(A).)

For the foregoing reasons, the Pacific Research Institute respectfully requests that the Court grant its application. In accordance with rule 8.520(f)(5), the proposed brief is attached.

Respectfully submitted,

/s/ Richard A. Epstein

Richard A. Epstein
16 Thomas Place
Norwalk, CT 06853
Counsel for *Amicus Curiae*

TABLE OF CONTENTS

TABLE OF AUTHORITIES

United States Supreme Court Cases

State Cases

Statutes and Restatements

Regulations

Other Authorities

Summary of Argument

The pharmaceutical industry is one of the most heavily regulated industries in the United States. This movement started with the Biologics Control Act of 1902 (32 Stat. 728) and expanded thereafter with the Federal Food, Drug, and Cosmetics Act of 1938 (52 Stat. 1050) (regulating safety), and, last, the Kefauver-Harris Amendment of 1962 (Pub. L. 87-781, 76 Stat. 780) (regulating effectiveness). Today, federal regulatory oversight covers the entire life-cycle of pharmaceutical innovation which includes identifying, creating, testing, marketing, and prescribing these regulated drugs. Right now, the law requires for all new drugs three stages of ever more expensive clinical trials, which many drugs enter, but from which only a few drugs successfully emerge. FDA approval is denied about 88% of the time, often after multiple, exhaustive submissions. Many other drugs are abandoned long before any approval process is undertaken. Investment in new drugs is always a high-risk, high-stakes game.

For each approved drug, the FDA regulates quality control, labeling, sales promotion, off-label uses, post-marketing review, and generic drug entry. The FDA has at its disposal a full menu of administrative remedies to prevent improper drug distribution, including injunctions, recalls, and criminal liability. An extensive body of antitrust law deals with potential collusion among drug companies. The Hatch-Waxman Act (The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585) governs the complex process of introducing generic drugs. State tort law exposes drug manufacturers to extensive liability even for drugs that have complied with FDA warnings. (*See Levine v. Wyeth* (2006) 183 Vt. 76, *aff'd* (2009) 555 U.S. 555.)

That strong regime of liability has held firm even though much empirical evidence has long suggested that the greater danger to public health lies in keeping good drugs off the market, not in letting dangerous drugs onto the market because the "benefits forgone on effective new drugs exceed greatly the waste avoided on ineffective drugs." (Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments* (1973) 81 J. POL. ECON. 1049, 1052.) Indeed, any decision to keep a drug off the market is difficult to correct by downstream physicians who could, as the FDA cannot, combine their unique knowledge of how the drug relates to the patient to select the optimal form of treatment. (Epstein, Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation (2006) at pp. 113-39.) In addition, a thriving market for physician-directed, off-label use of FDA approved drugs supplies a large portion of the treatment for such common maladies, including cancer, cardiac conditions, ulcers, and anticonvulsants, whose drug company promotion is still subject to FDA supervision.

Notwithstanding this massive government oversight through legislation, administration and litigation, there has *never* been, until this misguided case, any effort by *any* state court to allow juries to impose vast damage awards, easily amounting many billions of dollars, because of their unguided, after-the-fact intuition that the defendant chose to develop and market a new set of highly successful drugs in the *wrong* sequence. Indeed, Defendant's development took place seven years apart. Yet just that audacious tack is taken here for two critical classes of antiviral drugs used for treating HIV, hepatitis, and other related diseases.

Nonetheless, Plaintiffs claim that their harms stem from one common cause—the allegedly premature, i.e. earlier, development of "bad drug" tenofovir disoproxil fumarate, TDF, which has for two decades successfully helped millions of sick individuals cope with HIV and related

conditions. TDF has two well-known and fully disclosed side effects, related first to bone density and second to kidney function. (1App.151; 2App.480, 487-88.) The probability of TDF users suffering from either of these conditions is vanishingly small, affecting 0.002% and 0.11% of the millions of patients, respectively, per year. (7App.2355, 2358-60.) From the beginning, the FDA-approved label has alerted patients and physicians to the potential side effects. (10App.3102.) Those warnings are not challenged in this lawsuit because they are known to be adequate for both patients and physicians on when and how to use TDF. Plaintiffs acknowledge that no one has ever suggested that the FDA should withdraw TDF from the market, when to the contrary it continues to be sold and promoted as safe and effective in both its proprietary and generic forms. (10App.3103.) The Plaintiffs' sole claim is that it does not matter that TDF is still regarded as safe, effective, and approved for use (*see* COA.Arg.Tr. 41), or that, on this unambiguous record, the regulatory system has scored one of its greatest triumphs. Instead, these plaintiff lawyers now wish to upend this comprehensive scheme by seeking massive compensation for the Plaintiffs who joined individually in this lawsuit, each offering disputed individual factual claims of suffering from these bone and kidney side effects, for which they now demand millions in monetary compensation. Yet to allow this case to go to trial both risks bankrupting this Defendant and sends a strong signal to other pharmaceutical companies to swear off developing new drugs given the crushing liability that could follow their medical and commercial successes.

To achieve that disastrous result, the Plaintiffs have attacked the current system from the outside. They rely on an odd assortment of unrelated California cases to insist that it is proper to impose liability under California law on drug products that are no sense defective. These decisions hold that any given defendant can be found liable for some product-related

injury that is not caused by a product defect. Such cases can be found, but none of them bear the slightest resemblance to these cases. One such common case involves the negligent entrustment of a well-made, loaded gun to an infant unskilled in the use of firearms, who thereafter shoots an innocent stranger. (Restatement Third Of Torts: Liab. For Physical Harm (Basic Principles) (§ 7)) ("[A] person who turns over a firearm to a child who lacks special training and experience is subject to tort liability under the doctrine of negligent entrustment."); *Sullivan v. Creed* (1904) Ir. R. 317 (K.B.); *see generally* Epstein, Torts (1999) § 5.5.) But note the massive points of difference. The child acts in incomplete ignorance of what he has done, and his actions offer no hint of benefit to anyone else, which is why parents are required, often on pain of criminal liability, to keep deadly weapons out of harm's way. The downstream physician who prescribes these drugs is, in contrast, a fully trained professional with great skill and exhaustive information about a product that *universal* medical standards recommend for general use in treating patients in an institutional setting filled with multiple safeguards against misuse. Skilled doctors are not rogue children. Nor are they the psychotics, hardened criminals, or reckless teenagers, chronically depressed patients that populate the Plaintiffs' weird assortment of supposedly relevant cases.

So the simple question is—should these Plaintiffs use litigation to dictate the proper development and use of drugs? To which the answer is a resounding "No!" Those choices properly rest with experts at all stages of development, distribution, and use. But these patients, who have benefited from their care and treatment, now claim full compensation, ex post, for any expected harm of which they have been fully warned before accepting treatment. Now put that proposition to any drug company, by asking whether it would have made any drug if it knew *in advance* that its entire revenue stream could easily be diverted to pay compensation to the tiny

number of individuals who suffer from either kidney or bone disease, when even those known side effects may well be less harmful than dying or suffering from HIV. Any public-spirited company will flatly and emphatically turn down the offer to take prudent business risks if its medical triumphs result in its imminent ruination, which these Plaintiffs seek to bring about.

But what about the present and future generations of other patients? Suppose that they too are asked *in advance* whether they would demand compensation ex post at these ruinous levels before taking the drug. Their answer will be an emphatic "No!" if they are told that what seems like a good deal for them will result in no treatment. At this point, all patients and physicians will recognize that they receive ample in-kind compensation for any future loss from known adverse side effects, given that the odds are at least 500 to 1 that they will gain massive benefits from the drug.

But those amazing medical successes are not good enough for the plaintiff lawyers. They receive not one dime if all patients and physicians gain from successful cooperative arrangements with Gilead. But those same lawyers will make a veritable fortune if, after the fact, they can disrupt a successful market even this one time. So here is the irony. The Complaint charges that "Gilead withheld development of its safer product tenofovir alafenamide fumarate (TAF), to artificially and unreasonably maximize profits on its TDF-based medications first." (Complaint ¶ 2.) No, what has happened is that these lawyers have brought an outrageous lawsuit to artificially and unreasonably maximize *their* personal profits with their TDF-based litigation. They do so notwithstanding the grave threat that their lawsuit poses to the discovery, production, and marketing of *every* pharmaceutical product if these Plaintiffs, as the Court of Appeal held, have stated a claim sufficient to reach the jury. At this point, the looming threat of vast trial preparations and huge verdicts will force Gilead to accept large

settlements that will cripple its future efforts to produce more blockbuster drugs like *both* TDF and TAF.

Nonetheless, Plaintiffs argue that there is some supposed original sin in letting new drugs go onto the market in the wrong order. It is as though Gilead had complete control over this choice, even though the opportunity to develop TDF appeared years before TAF became an attractive candidate for further development. And the Plaintiffs ignore how a highly uncertain approval process (never applicable in cases of misconduct by infants, criminals, or psychotics!) may result in delay or denial after that manufacturer has committed many millions of dollars to bringing the product to market, and therefore it has to be prescribed by an informed physician to a concerned patient who often actively participates in drug selection. The Plaintiffs' improbable claim is that it is "foreseeable," even "highly foreseeable," that the "wrong" choice should be subject to jury retribution. It is factually wrong for the Plaintiffs to claim the Defendant knew that they had an unambiguously superior prodrug[1] tenofovir alafenamide fumarate or TAF, which was said to be "more efficacious and less toxic to kidneys and bones than TDF." (Complaint at ¶ 1.)

In order to assess this novel claim, therefore, it is necessary to deal with both legal and factual issues. The chief legal question is whether the Defendant had a common law duty to alter the order of production of the two drugs under California law (as if that could be done in 2004 when TDF was already on the market as of 2001). That is a legal question for this Court now to resolve. Baked into this case is the Plaintiffs' false narrative,

[1] *See* American Heritage Dict. (5th ed.) (defining a prodrug as "1. Any of various drugs that are administered in an inactive form and converted into active form by normal metabolic processes. 2. A drug that is administered in an inactive form that is metabolised in the body into a biologically active compound.").

which was accepted by the Court of Appeal in its decision. Normally questions of fact dealing with the sufficiency of the complaint should not be raised on appeal. But this case offers an important and well-established exception to the rule. The only facts that are needed to discredit the Plaintiffs' narrative are readily available in the public record. That evidence conclusively discredits the Plaintiffs' contrived narrative. The public record contradicts the claim that a superior drug was suppressed in breach of the Defendant's duty to its patients. There is nothing to support Plaintiffs' claim that the Defendant (without specifying a year) "deliberately chose to sell its TDF drugs first so that Gilead could reap the benefits of those sales and then later market its safer TAF drugs as a 'product hop' or a life cycle extension that would effectively monetize both drugs." (Complaint at ¶ 1.) In fact, both drugs are still on the market; their uses are complementary so that it is impossible to establish that one is "safer" than the other. Nor is it possible to treat these two drugs as if they occupy some unique Gilead space. They both are sold in competition with many other similar drugs produced by other manufacturers that are both highly recommended and commonly used to treat the same set of various HIV-related conditions. In any event, the notion of product hopping only applies when the manufacturer of a drug whose patent has expired seeks to make small changes to its formula to forestall generic competition, *see infra*, that is not remotely satisfied here. It is not only proper but imperative for this Court to take judicial notice of undisputed facts in the public record. (*See* Evid. Code, § 45(f) (allowing courts to consider "[f]acts and propositions of generalized knowledge that are so universally known that they cannot reasonably be the subject of dispute").)

ARGUMENT

I. The Defendant in this Instance Did Not Owe Any Generalized Duty of Care to the Plaintiffs to Expedite the Production of TAF as Some Hypothetical "Safest Drug Available."

Under California law, the question of "[w]hether a duty [of care] exists is a question of law to be resolved by the court." (*Brown v. USA Taekwondo* (2021) 11 Cal. 5th 204, 206, *quoting Bily v. Arthur Young & Co*. (1992) 3 Cal.4th 370, 397.) One of the basic tools used to analyze this question is Civil Code 1714 that provides in relevant part:

> Everyone is responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter has, willfully or by want of ordinary care, brought the injury upon himself or herself.

That statutory provision, however, does not cover the entire waterfront because it makes no reference to strict liability rules in connection with product liability cases. (*See Escola v. Coca Cola Bottling Co. of Fresno* (1944) 24 Cal.2d 453, 459; *Greenman v. Yuba Power Products, Inc.* (1963) 59 Cal.2d 57, 61.) Neither of these seminal cases mentions Section 1714 in the development of the strict liability rule, precisely because that Section contains no reference to any strict liability principle, but only covers torts of negligence and intent.[2] Omitting strict liability torts from that Section is thus a faithful reading of that provision,

[2] The pattern is in fact pervasive, for none of the generative product liability cases mentions, let alone relies on, Section 1714. (*See, e.g*., *Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413; *Cronin v. J.B.E. Olson Corp*. (1972) 8 Cal.3d 121; *Pike v. Frank G. Hough Co.* (1970) 2 Cal.3d 465.)

which *never* involves situations where a particular defendant is charged from exploding Coca-Cola bottles, or defective lathes, or indeed, any poisonous pharmaceutical product, because *none* of these defendants was in possession of a defective product at the time when its use caused harm.

In contrast, *all* the cases that do fall under Section 1714 involve some *contemporary* activity or oversight of the activities at the time the injury occurs. The early Section 1714 cases involve such matters as occupiers' liability or notary publics, which have long created liability in other states without any difficulty but faced doctrinal challenges in California courts due to Section 1714's influence in the articulation of tort doctrine. (*See Rowland v. Christian* (1968) 69 Cal.2d 108; *Biakanja v. Irving* (1958) 49 Cal.2d 647.) But *all* the current cases of relevance none of which are product liability cases—deal not with the direct wrong that one person commits against another, but with situations where the responsibility of some institutional defendant to exercise some reasonable oversight of the actions of *other* individuals. Many of these individuals have committed such obvious wrongs as physical or sexual assault for which they cannot pay compensation. Faced with no solvent first-tier defendant, every court, in California and elsewhere, now has to ask the far harder question of whether some second-tier defendant has to take up the slack in order for the injured party to obtain any compensation at all. The cases on this vexed topic are numerous, and they come out both ways: some allow liability against some, but not all, defendants while other cases do not. The jumble of half-sentence quotations that constitutes the bulk of the Plaintiffs' brief never once mentions (let alone discusses) *any* case that has rejected liability in these oversight cases for any reason, which renders its analysis worthless. Hence it is necessary to set the record clear to review the key cases in some detail.

The origin of the current inquiry starts with language that was first introduced in *Biakanja*, which was then carried forward into *Rowland,* which identified several considerations that may, on balance, justify a departure from Section 1714's default rule of duty.

> A departure from this fundamental principle involves the balancing of a number of considerations; the major ones are the foreseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant's conduct and the injury suffered, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost, and prevalence of insurance for the risk involved.

(*Rowland*, *supra,* 69 Cal.2d at p. 113.)

The effort to apply this general formula to a wide variety of cases has been a major issue before this Court since 1968, yet the words of that passage themselves do not clearly articulate how to conduct this analysis. Much clarity and simplification has been added by the recent case of *Kuciemba v. Victory Woodworks*, *Inc*. (2023) 14 Cal. 5th 993, which held that as a first approximation these *Rowland* factors were of two types. The first type concerned the "foreseeability factors" and the second concerned the "policy factors." A plaintiff has to prevail on both issues to impose a duty of care. (*Id*. at pp. 1021-22; *see also Kesner v. Superior Court* (2016) 1 Cal.5th at p. 1149.)

As this Court said in *Brown*, the general principle contained in Section 1714 "states a broad rule, but it has limits." (*Brown*, *supra,* 11 Cal.5th at p. 214.) That statement is borne out by an examination of the facts in *Brown* itself, where three female gymnasts had been for years sexually molested by their coach Marc Gitelman, who for his odious misconduct was first banned from coaching and then convicted of multiple

felonies. The legal question was whether a duty of care to guard against his misconduct attached to either or both organizations, USA Taekwondo (USAT) and the United States Olympic Committee (USOC). In its decision, the Court held first that there was no special relationship between the USOC and the plaintiffs, and it thus refused to engage in a detailed analysis of the various *Rowland* factors, because it explicitly endorsed the position of the intermediate court that the defendants were one degree too far removed "to control Gitelman's conduct, or that would give plaintiffs reason to look to the USOC for protection." (*Id.* at p. 212.) That organization had no direct connections with any of the athletes, for its mission was directed exclusively toward the U.S. participation in Olympic activities. That same degree of separation did not hold for USAT, which occupied a direct oversight position "to control Gitelman's actions, as demonstrated by the fact that USAT had registered him as a coach, took disciplinary action against him, and ultimately barred him from coaching." (*Ibid*.)

It is, of course, quite clear that in some unmoored sense, both organizations could equally "foresee" that something could go awry in the coaching arrangement. There is no doubt that the USOC understood some coaches could abuse female athletes at some time. Anyone who reads the newspapers also knows this fact, which explains why some generalized level of foresight has never been sufficient to establish the first half of the duty determination. It was the immediate, direct, and contemporaneous *control* by USAT of the coaches that showed that USAT had both the means to oversee these operations and, moreover, had assumed that responsibility. Indeed, one reason why the USOC escapes a duty under the foresight inquiry is that it knows that the USAT has that responsibility to do just that, which makes it unwise and unnecessary to treat the USOC as if it

had the same level of control. The intermediate control exerted by USAT negated any USOC duty to the gymnasts.

The policy factors cut in the same way. Given the physical and social distance from the places of actual harm, this Court rightly insulated the USOC from all liability by applying the basic common rule that "one owes no duty to control the conduct of another, nor to warn those endangered by such conduct." (*Brown*, *supra,* 11 Cal.5th at p. 216, quoting *Regents of University of California v. Superior Court* (2018) 4 Cal.5th 607, 619.) The story in *Regents* exhibited a very different control relationship. Here the defendants were in charge of a university when the plaintiff was stabbed in a chemistry lab by a fellow student whom the university already knew suffered from auditory hallucinations and who was awaiting mental health treatment. The tightness of the control made this an easy case for liability on foresight grounds. Yet on the policy level, it was wholly unlikely that universities would withdraw from affording mental health treatment to its students, given the other constraints on its behavior, when its obligations under the Americans with Disabilities Act were coupled with a set of powerful "market forces," both requiring the university to take overall charge of the situation. (*Id*. at p. 632.) Indeed, the plaintiff's case here is stronger than that against USAT in *Brown* given that the Regents had direct information of the mental condition of the distressed student whose activities it had to monitor.

The next pair of cases involves the potential liability of employers for injuries caused, not to their employees, but to third parties outside the workplace who were injured by contact with dangerous substances generated inside the workplace. Once again, the Court stressed the importance of immediate and contemporaneous control over the harm in evaluating the duty of care. In *Kesner v. Superior Co*urt, (2016) 1 Cal. 5th 1132, the plaintiff's husband carried home asbestos fibers from the

workplace, where they exposed her to injury. The question of causation and foresight was never in issue because this precise risk had been identified in OSHA regulations, which specified the correct set of protections for employers to take to prevent the spread of these fibers in the home environment. Hence, the breach of that independent federal standard generated the duty when there was no new or intervention activity to break the chain of causation. The court thus rejected any "categorical exception" to this statutory duty to take care. Yet given the application of the policy factors, the Court split the difference, holding that, in light of the huge potential risk of unlimited third-party liability, recovery should only be allowed to members of the employee's household where the "regularity and intensity was highest." (*Id.* at p. 1141.) The compromise solution found employer liability in the most important cases without exposing it to an unlimited liability that could sink the company.

That intermediate solution proved unavailing in *Kuciemba v. Victory Woodworks*, (2023) 14 Cal.5th 993, where Corby Kuciemba's husband, Robert, was an employee of Victory Woodworks when a health order by the City and County of San Francisco placed him in proximity with other workers. Robert became infected and brought the virus home to his wife who suffered a serious bout of COVID from which she eventually recovered. Although she was a member of his household, her tort action against the employer was barred. Although the explicit violation of a county health ordinance counted in favor of liability, it was overridden by other factors that arose outside the defendant's workplace "such as mask wearing and social distancing," and the employer cannot "control whether a given employee will be aware of, or report, disease exposure." (*Id*. at p. 1026.) In addition, "[t]here is also a possibility that imposing a tort duty not covered by workers' compensation could lead some employers to close down, or to impose stringent workplace restrictions that significantly slow

the pace of work." (*Id*. at p. 1027.) And last, there was the prospect of crushing liability that could apply even within that limited class of household members.

Plaintiffs' case is controlled by *Kuciemba,* not *Kesner*. On the initial causation question, the Defendant had only limited control over COVID or any FDA drug to treat it. Nor was there any independently enforceable legal norm that paralleled the OSHA regulations in *Kesner* or the COVID regulations in *Kuciemba*. In the absence of any breach of a legal duty, the plaintiffs invent an imaginary moral duty to do what is impossible in medicine, namely create a risk-free product that will dominate the market.

In addition, there is the near certainty that any such supposed duty will upset the delicate balance on drug introduction as set by dozens of rules and years of practice through the FDA regulation of new drugs. This last risk moved this court in yet another Section 1714 case, involving financial losses, to avoid creating independent duties that do not mesh with established practice. Thus, in *Sheen v. Wells Fargo Bank, N.A*. (2022) 12 Cal.5th 905, the plaintiff, whose loan had been foreclosed, argued that the bank "owed Plaintiff a duty of care to process, review and respond carefully and completely to the loan modification applications Plaintiff submitted." (*Id.* at p. 914.) This Court unanimously rejected that claim, citing *Brown v. USA Taekwondo*, noting that it was unwise to inject an independent tort duty into a relationship that was already fully determined by contract. It did so, moreover, for institutional reasons fully applicable here, related to the economic loss doctrine. This "judicially created doctrine bars recovery in negligence for purely economic losses when such claims would disrupt the parties' private ordering, render contracts less reliable as a means of organizing commercial relationships, and stifle the development of contract law." (*Id.* at p. 915.) As in this case, the Plaintiff could not cite any statute or regulation that embodied the supposed duty that addressed the processes

mortgage servicers must follow with regard to handling modification applications, including the California Homeowner Bill of Rights. (Civ. Code, § 2923.4 et seq.) In words that are fully applicable here, the Court declined to impose a common law duty:

> Plaintiff recognizes that lawmakers at both the state and federal levels have been active in regulating the mortgage loan modification process. . . . In contrast with such detailed schemes, tort liability—with a yet-to-be articulated standard of care—is ill defined and amorphous. We remain uncertain how such differing regulatory and statutory frameworks will function in practice, much less that they might operate together to better serve the interests of borrowers, lenders, or the public at large. The vagueness and breadth of plaintiff's proposed duty thus counsel against imposing that duty to correct for the problems he contends exist.

(*Sheen*, *supra,* 12 Cal.5th at p. 944.)

What is true here, is also true in this non-contractual context dealing with the integration of the supposed new duty with the current operations of the FDA. Clearly, any supposed duty should, if undertaken at all, be a legislative matter. Indeed, the level of direct regulation is so pervasive that although the issue is not before this Court, the Plaintiffs' novel theory appears preempted by federal law under the seminal case of *Rice v. Santa Fe Elevator Corp.*, (1947) 331 U.S. 218. It observes that "[t]he scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it. (*Id*. at p. 230.)

II. Reasonable Foresight, Which in Other States is the Common Law Basis for Establishing Duty of Care, Tracks Civil Code Section1714.

An unmoored foresight test has also been rejected in federal cases governing environmental harms. As originally enacted, the National Environmental Policy Act (NEPA), required agencies to prepare an environmental impact statement (EIS) for all proposals of "major Federal

actions significantly affecting the quality of the human environment" to analyze "the environmental impact of the proposed action." (42 U.S.C. § 4332(C).) Those potential impacts, like the release of either asbestos or COVID 19, can extend indefinitely both backward and forward in time, which means that some additional principle must be invoked to limit a potentially open-ended scope of action. The original 1978 CEQ Regulation defined the "Effects" to include both "(a) Direct effects, which are caused by the action and occur at the same time and place," and "(b) Indirect effects, which are caused by the action and are later in time or farther removed in distance, *but are still reasonably foreseeable*." 43 Fed. Reg. 55978, 56004 (Nov. 29, 1978) (emphasis added), which in 2023, was included in the Fiscal Responsibility Act that requires agencies to study these "reasonably foreseeable environmental effects of the proposed agency action." (42 U.S.C. § 4332(C).)

The question of what force should be given to the term "reasonable" in this statute arose in *Metropolitan Edison Co. v. People Against Nuclear Energy* (1983) 460 U.S. 766. The Nuclear Regulatory Commission (NRC) had authorized the restart of one of the idle reactors at Three Mile Island. The NRC then concluded that this decision would not have any significant environmental impact. That decision was challenged on the ground NRC had failed to consider psychological harm from reopening the site to residents in the vicinity, and their relatives anywhere else. No one could deny that these reactions were in some sense "foreseeable." Yet these psychological harms were held to fall outside NEPA because the notion of foresight was capped by the principles of causation articulated at common law, a "requirement [that] is like the familiar doctrine of proximate cause from tort law." (*Id*. at p. 774.)

The Court continued that "[i]n the context of both tort law and NEPA, courts must look to the underlying policies or legislative intent in

order to draw a manageable line between those causal changes that may make an actor responsible for an effect and those that do not." (*Id*. at p. 774 n.7.) It concluded that "[t]ime and resources are simply too limited for us to believe that Congress intended to extend NEPA as far as the Court of Appeals has taken it. The scope of the agency's inquiries must remain manageable if NEPA's goal of "[insuring] a fully informed and well-considered decision," (*id*. at p. 558), is to be accomplished. (*Id.* at p. 776.) That proximity condition cannot be satisfied given the vast array of actions that intervene between the initial action and its asserted effect.

Thus, there is no sharp discontinuity between *Metropolitan Edison* and California case law under Section 1714. Both use traditional common law techniques to limit the principle of reasonable foresight so that it does not leap over all interventions, actions, and omissions between the initial conduct of the defendant and the harm complained of by the plaintiffs. Indeed, just that result should be expected. The underlying structural issues are identical, for as causal chains become more attenuated, downstream actors should bear more of the liability, no matter the basic liability. Thus, in *Tarasoff*, *supra,*178 Cal. 3d at p. 425, the question was whether a therapist who saw a troubled patient owed a duty of care to a woman he mentioned in therapy, whom the patient promptly murdered upon his release. The Court cited both *Rowland* and Section 1714, but with this instructive qualification, "when the avoidance of foreseeable harm requires a defendant to control the conduct of another person or to warn of such conduct, *the common law* has traditionally imposed liability only if the defendant bears some special relationship to the dangerous person or to the potential victim." (*Tarasoff v. Regents of University of California,* (1976) 17 Cal. 3d 425, 435 (emphasis added).) The logic is the same without or without Section 1714.

That same close interdependence between common law and Section 1714 is evident in *Bily v. Arthur Young & Co.* (1992) 3 Cal.4th 370, as modified (Nov. 12, 1992), where the question was "whether and to what extent an accountant's duty of care in the preparation of an independent audit of a client's financial statements extends to persons other than the client." (*Id.* at p. 375.) The case began by quoting Chief Judge Cardozo's "seminal opinion," in *Ultramares Corporation v. Touche* (1931) 255 N.Y. 170, which imposed a limited liability given the fear of "an indeterminate amount for an indeterminate time to an indeterminate class." (*Bily, supra,* 3 Cal.4th at p. 385; *Ultramares, supra,* 174 N.E. at p. 444.)

As a result, in New York, liability has been eventually restricted to cases where the accountant must have been aware that the financial reports were to be used for a particular purpose or purposes with known reliance on known parties that is linked to the accountant's reports. (*Bily,* 3 Cal. 4th at p. 387). This rule, which dovetails seamlessly into Section 1714, results in the same targeted exposure. (*Id.* at p. 421 ("To recover damages for an accountant's negligence in rendering an unqualified audit opinion, a plaintiff must prove both reliance on the audit opinion and a factual nexus between the plaintiff's loss and the undisclosed defects in the audited financial statements.")))

These are major cases that weave Section 1714 and common law principles together, and all undercut the Plaintiffs' extravagant claims of the distinctive influence of that Section.

III. The History of Section 1714 Shows its Close Affinity with Common Law Rules and Fatally Undercuts Plaintiffs' Incorrect Claim that the Defendant is Under a Duty to Develop any Particular Drug, Including TAF, in any Particular Order.

The famous six-part verbal formulation of the Section 1714 factors, quoted *supra*, was first used without any prior citation in *Biakanja v. Irving,* when it was offered as an off-the-cuff summary of Prosser on Torts (1972) and Harper & James on Torts (1956). (*Biakanja, supra,* 49 Cal. 2d at p. 650.) Section 1714 was not cited at all. Instead, *Biakanja* showed the close connection between California case law, relying on the famous New York case of *Glanzer v. Shepard* (1922) 233 N.Y. 236, written by Judge Cardozo. (*Biakanja, supra,* 49 Cal. 2d at p. 650.) A public weigher employed by the seller of beans had to refund the excess charge imposed on the buyer with whom he was not in privity when his scales malfunctioned. *Glanzer* was relevant to *Biakanja*, where the plaintiff was supposed to receive all the property left under the will of his late brother. Unfortunately, the notary public failed to execute the proper paperwork, so the plaintiff received only one-eighth of the estate. The question arose whether he could recover the remainder from the notary when recovery was barred against the other beneficiary under the will. The court gave the nod to the disappointed heir because the defendant could have avoided the mix-up by following standard procedures. The transaction took place at a single point in time; the precaution was standard practice, and the damages were liquidated. *Glanzer* anticipates *Biakanja,* which thus falls seamlessly into the common law.

The basic formulation was then put to more ambitious use in *Rowland,* but the actual opinion did not change the common law rule one iota. The basic common law position holds that the liability of an occupier to a social guest (or licensees) on premises is less stringent than it was to an invitee (visitor on business premises) and requires the premise owner to disclose latent defects to visitors who made ordinary use of the premises. And, precisely this failure to disclose latent defects occurred when Nancy Christian neglected to tell her overnight visitor James Rowland of the

defective porcelain faucet in the lavatory that then severed the nerves and tendons in his right hand. (*Rowland v. Christian*, 110.) The conventional analysis treats the defective faucet as a trap, whose benign appearance misled Rowland. Under Restatement Second of Torts (§ 342), the occupier must issue a warning if he or she does not make the condition safe. At the time, California law had not yet adopted that position, but instead treated a social guest like a trespasser who had to take defective premises as found, where the occupier only owes them the duty of refraining from wanton or willful injury. (*Rowland*, *supra*, 69 Cal.2d at p. 114.) The Court could have fixed the problem by rejecting the parity between trespassers and licensees and reverting to the common law rule governing latent defects and the social guest, which it declined to do.

The doctrinal tension in *Rowland* arose because the Court perceived that Section 1714 set some sliding scale of liability under *Biakanja* so that the use of fixed categories necessarily created a "departure from this fundamental rule of liability." (*Rowland*, *supra*, 69 Cal.2d at p. 113.) The *Rowland* Court then criticized the older rule as being out of touch with modern times. But the record contains no evidence that "an increasing regard for human safety has led to a retreat from this [i.e. the common law]" which was then derived on the ground that apart from spring guns, only to conclude that "the lack of definiteness in the application of the term 'trap' to any other situation makes its use argumentative and unsatisfactory." (*Id.* at p. 114-15.) The Court then erroneously concluded that "licensee and invitee were inherited from a culture deeply rooted to the land." (*Id.* at p. 116.) *Rowland* then posited that occupier liability rules could be traced to "a heritage of feudalism." (*Id.* at p. 113.) In fact, these were nineteenth-century distinctions. The rule for licensees was articulated in *Southcote v. Stanley* (1856) 1 Hurlst & N. 247, 156 Eng. Rep. 1195. The rule for invitees dates to *Indermaur v. Dames* (1866), L.R. 1, C.P. 274, 35

L.J.C.P. 184, *aff'd*. L.R. 2 C.P. 311, 36 L.J.C.P. 181, described by Prosser as the leading English case. (Prosser, Torts (4th ed. 1971) at p. 385.)

More recently, *Wolfson v. Chelist* (Mo. 1955) 284 S.W.2d 447, offered a careful historical review and strong defense of the basic common law classification, while noting that exceptions to it should be made whenever necessary. It explicitly rejected an invitation to eliminate the categories, and accordingly denied the plaintiff recovery when the defendant had not had time to discover "fragments of meat or grease which remained on the concrete porch floor after the cat had been fed there the night before." (*Id*. at p. 447.) Neither that case nor Prosser, nor any other source, contains a single reference to the supposed "feudal origins" of the tripartite classification. Prosser did not refer to *Rowland,* which was decided when his fourth edition was in press. *Biakanja* receives only two passing references, neither of which mentions its now famous quotation (Prosser, *supra,* at pp. 627, 952.)

Ironically, *Rowland* belatedly did adopt the common law approach on the relevance of traps writing, "Where the occupier of land is aware of a concealed condition involving in the absence of precautions an unreasonable risk of harm to those coming in contact with it and is aware that a person on the premises is about to come in contact with it, the trier of fact can reasonably conclude that a failure to warn or to repair the condition constitutes negligence." (*Rowland, supra*, 69 Cal.2d at p. 119.) A more accurate rule is that if the facts are as posited, there is no need for a jury trial, so that a directed verdict for the plaintiff is in order. (*Id.* at p. 120.)

Rowland itself never examined the relative strengths of the categorical approach of the common law tripartite division as against the sliding scale approach implicit under a literal reading Section 1714. However, those categorical rules provide guidance for broad classes of cases avoiding inconsistent judgments, without rudder or compass, with

individual jury verdicts. (*See Robert Addie & Sons (Collieries), Ltd. v. Dumbreck,* [1929] A. C. 358 (Scot).) Today, where the formal distinction between licensees and invitees is abolished at the wholesale level, it still works well at the retail level. Therefore, any trial counsel representing a residential property occupier is well-advised to insist that ordinary social expectations do not demand that an occupier supply greater protection to a licensee than to himself or his family. (*See* Epstein, Torts, §12.11 (1999) at p. 331.)

Note that the Court of Appeal's decision in *Gilead* glosses over all these key differences, for it does not even attempt to examine the incentive effects, error costs, and the costs of litigation—under either common law categorical approach or the factor test. Yet, the factual pattern in *Rowland* is worlds apart from *Gilead. Rowland* has only two parties to which it applies a time-tested simple rule; there was no public dissatisfaction with the tripartite classification of social guests, invitees, and regular invitees; no difficulty in its application; no possible way that it unhinges sound billion dollar investments that will take years to pan out, if they pan out at all. The plaintiffs deal in broad generalities because they know that any close comparisons between the two cases only reinforces the enormous gulf between them.

The subsequent history of Section 1714 confirms that it did not upend the standard expectations of either California or the general common law. Thus, in *Li v. Yellow Cab Co*. (1975) 13 Cal.3d 804, the Court "judicially declare[d]" that it was replacing the common law, which had long treated plaintiff's contributory negligence an absolute bar to recovery, with a rule of comparative negligence that "assesses liability in direct proportion to fault." (*Id*. at p. 807.) It then concluded that the statutory command of Section 1714 did not "codify" contributory negligence so as to block the change, stating "It was the intention of the Legislature to

announce and formulate existing common law principles and definitions for purposes of orderly and concise presentation and with a distinct view toward continuing judicial evolution." (*Id*. at p. 1233.)

These passages show that *Li* does not represent any sharp break from other jurisdictions, most of which both by legislation and judicial decision have switched to either the "pure" comparative form adopted in California or a 50-percent cutoff rule. The substantive arguments pro and con were the same in all jurisdictions, so that today some 46 states have adopted one of these variations of comparative negligence. (*See* Schwartz & Rowe, (5th ed. 2018) Comparative Negligence, Appendix A). *Rowland* has not prevented California's active judicial development of the twin concepts of proximate causation and duty of care, as is evident by all the cases examined above.

IV. The Plaintiffs Cannot Establish Any of the Factual Predicates for Their Novel Theory of Liability.

The Court of Appeal adopted an unheard-of theory of liability that held in essence that a plaintiff in a product liability case need not show that a challenged drug was defective in its fabrication, design, or warnings, under both FDA and common law standards.

The Plaintiffs' theory was introduced by a novel hypothetical that imagines Gilead breached its duty of care to potential users after it first launched TDF in 2001, because it discontinued further drug development on TAF in 2004. Work on TAF only restarted in 2011 with its delayed launch after receiving FDA approval in 2015. The plaintiffs claimed that this improper temporal gap resulted in some 25,000 deaths and injuries from bone and kidney disease that could have been avoided by an earlier (if

unspecified) launch of TAF, the superior product with both stronger curative properties and fewer side effects. In Plaintiffs' view, the only reason to resist the prompt development and sale of TAF was to milk monopoly profits from the earlier TDF product before "product hopping" customers over to TAF, thereby continuing Gilead's monopolization into a second generation. The Court of Appeal held that on this record, Gilead's liability could also be established by showing that Gilead was negligent—or worse, willful and fraudulent—in concealing the truth from the public, solely to obtain illicit monopoly profits from TDF until TAF hit the market in 2015.

The account is pure myth for there are no monopoly profits for any drug in this competitive marketplace. The Plaintiffs appeal to the notion of "product hopping," which is wholly out of place in this context. A recent Federal Trade Commission report explains why:

> Product hopping is a strategy where a brand-name pharmaceutical company seek to shift demand from a brand-name drug that faces generic competition to a newly patented and/or exclusivity protected drugs that do not face generic competition. For example, a product hop can be executed by making modest non-therapeutic changes to a product that offer little or no apparent medical benefit to consumers and moving demand to that product.

(Report on Pharmaceutical Product Hopping (2022), https://tinyurl.com/2fh9zx6t.)

The entire report stresses how small modifications in brand-name drugs can stifle the entry of generic competition. None of the report refers to supposed cases where a company is said to stage the delayed entry of a second major new chemical entity—which TAF surely is relative to TDF. The FDA report offers instances of generic product hopping (Ovcon, Doryx, Suboxone) all of which involve moving from one product to a different product with insignificant differences in therapeutic effect, solely

to avoid generic competition. It makes no mention of the transition from TDF to TAF, completed by 2015.

The so-called Orange Book[3] also contains a list of "reference standard drugs that generics seeking to file an Abbreviated New Drug Application (or ANDA) must serve, as the name implies, as the reference for the new drug.[4] That standard can only be withdrawn for a determination that the drug no longer meets the standards of safety and effectiveness, which not an issue with TDF. Gilead would never try to execute a maneuver to ban its own drug, so that other companies can enter the generic market and thus undercut any supposed monopoly power. Given these powerful institutional constraints, the imaginary product could never be executed. Nothing that Gilead could have done could have prevented the entry of other drugs by other producers of antiviral drugs that compete with both TDF and TAF. There is a zero-sum possibility that some product hop could be executed.

Thus, the gist of the Plaintiffs' improbable case is stated in the opening paragraph of their complaint, (Complaint at ¶2), and received its "hypothetical" endorsement in the appellate court in this exchange.

> Let's make the facts a little bit more egregious and say, okay, so Gilead reduced – or released TDF, and then a couple of years later as it was developing TAF, they started to have this conversation about whether or not it would make sense to pause TAF's development for purely profit reasons.
>
> And as part of that discussion, executives asked for an estimate on, okay, well, if we did that, *how many people would actually be injured from TDF that would not be injured from TAF.* And so, they crunched the numbers, and they came

[3] FDA, A*pproved Drug Products With Therapeutic Equivalence Evaluation* <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface>

[4] Id. at 1.4 Reference Listed Drug and Reference Standard.

> back with a hard estimate, 25,000 people would be injured or killed - 5,000 killed, 20,000 injured.
>
> And the company said, okay, let's pause it and we'll just accept that. And to make it even more egregious they could say, how much money will we make, and they crunched those numbers and they come back, and they say, well, even if we're stuck with liability for paying those claims, *we'll still make $5 billion more if we pause TAF. . . .*
>
> When the Court sought to clarify, asking: "So, under the hypo I gave you when ***Gilead actually calculated precisely how many people would be injured by their product and they decide to pause it anyway***, and you know, potentially pay those claims just because they're going to earn more money. You're saying there's –that's - the law doesn't reach that at all. You can't challenge it. They're immune to that kind of liability," Gilead's counsel responded: "**So, yes, that is correct**."

(Plaintiffs' Amicus Briefs, 2023 CA App. Ct. Briefs. (quoting OA.62:10-19) (emphasis added.)

"Correct" is indeed the right answer, but not just for reasons that the Defendant offered to explain how Plaintiffs' theory undercuts the comprehensive regulatory powers of the FDA. A complete reply adds two key points. The first is that the evidentiary record offers no support for the alleged "product hopping" claim that created two successive monopolies in these distinct two products, each a new chemical entity (NCE)—that is, a novel chemical compound that has not been previously approved for human use by any regulatory authority. The second is that both products had complementary uses, and thus at all times were sold in markets with multiple competitors. Indeed, TDF remains a strong competitor to TAF long after its patent protection expired.

To see why this is the case, break the Complaint down into its component parts. Start with a terminological point. The plaintiffs write as

if Gilead enjoyed "an exclusive and extremely profitable monopoly on TDF [marketed as Viread] for some 15 years." (Complaint at ¶2.) Wrong. Patent law does not give any patentee a monopoly over any patented product, let alone a monopoly treating either HIV or Hepatitis B, the viruses to which TDF is targeted. (*See Illinois Tool Works Inc. v. Independent Ink, Inc.* (2006) 547 U.S. 28. (denying that a patent gives monopoly power to support a tie-in case).) What a patent gives the patentee is the exclusive right to sell that patented product. The sales of a patented drug may be highly profitable because of the large size of the market and the great efficacy of the drug. But at all times, other manufacturers could sell their antiviral drugs in competition with TDF, whether or not TAF was then on the market. Profitable drugs do not generate illicit monopoly profits.

Plaintiffs seek to bolster their unsubstantiated claim of monopoly power by noting that in 2006, Gilead expanded its supposed monopoly position by releasing one of several combination drugs, Atripla. (Complaint at ¶ 90.) Introducing the second product necessarily cannibalizes part of the market for the original drug, but it works to great advantage to consumers by increasing their drug options, given that Atripla works in competition with both TDF and TDF's rivals sold by other firms. It is no wonder Atripla's release did not provoke any antitrust response by federal government, state governments, or private parties.

Nor does it matter that Gilead purchased the exclusive rights to manufacture the TDF class of compounds from Bristol-Meyers (later merged with Squibb to make BMS). BMS sold its rights to the TDF class of compounds to Gilead because BMS had lost confidence that tenofovir had commercial value. (*Id*. at ¶¶31-34.) But far from being improper, that transfer represents the efficient operation of the pharmaceutical marketplace. Gilead then hired the BMS physician, Dr. John C. Martin, who had championed its potential value. The Plaintiffs then falsely claim

that Gilead had entered into "anti-competitive" deals with a wide range of companies, including BMS, to develop such compound products, including Atripla. (Complaint at ¶11.) But expanding the number of products in the market enhances competition rather than suppresses it.

The next part of Plaintiffs' monopoly story is every bit as improbable. To see why, consider sales data of the various TDF and TAF products from 2012 to 2023.

Table 1

				U.S. Revenues ($ millions)												
Manufacturer	**Drug**	**TDF / TAF**	**Generic Entry**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**Total**
Gilead	Viread	TDF	Dec-17	387	428	484	541	591	514	50	32	14	11	6	8	**6,381**
Gilead	Truvada	TDF	Oct-20	1,612	1,570	1,787	2,057	2,384	2,266	2,605	2,640	1,376	314	113	82	**25,798**
Gilead	Atripla	TDF	Oct-20	2,252	2,355	2,357	2,222	1,898	1,288	967	501	307	121			**22,265**
Gilead	Complera	TDF	n/a	280	503	663	796	821	406	276	160	89	102	74	47	**4,255**
Gilead	Stribild	TDF	n/a	57	509	1,014	1,476	1,523	811	505	268	125	132	88	72	**6,580**
Gilead	Vemlidy	TAF	n/a						111	245	309	356	384	429	410	**2,244**
Gilead	Descovy	TAF	n/a					226	958	1,217	1,078	1,526	1,397	1,631	1,771	**9,804**
Gilead	Biktarvy	TAF	n/a							1,144	4,225	6,095	7,049	8,510	9,692	**36,715**
Gilead	Genvoya	TAF	n/a				44	1,301	3,033	3,631	2,984	2,605	2,267	1,983	1,752	**19,600**
Gilead	Odefsey	TAF	n/a					302	964	1,242	1,180	1,172	1,076	1,058	1,012	**8,006**
Gilead	**Total TDF**	**TDF**	**n/a**	**4,588**	**5,365**	**6,305**	**7,092**	**7,217**	**5,285**	**4,403**	**3,601**	**1,911**	**680**	**281**	**209**	**65,279**
Gilead	**Total TAF**	**TAF**	**n/a**	**0**	**0**	**0**	**44**	**1,829**	**5,066**	**7,479**	**9,776**	**11,754**	**12,173**	**13,611**	**14,637**	**76,369**
Gilead	**Grand Total**	**TDF & TAF**	**n/a**	**4,588**	**5,365**	**6,305**	**7,136**	**9,046**	**10,351**	**11,882**	**13,377**	**13,665**	**12,853**	**13,892**	**14,846**	**141,648**

TAF products first entered the market in 2015, and TDF went generic in late 2017 and early 2018. In December 2017, generic TDF had an estimated market size of $734.4 million. (*Aurobindo Receives FDA Approval for Tenofovir Disoproxil Fumarate Tablets*, AUROBINDO (Jan. 26, 2018), <https://tinyurl.com/9d3paend>.) Under a business deal with Teva, the latter company was allowed to market its generic version of the drug in December 2017. A month later, the generic market was fully open, so other companies also entered with their generic products, including Aurobindo, on January 26, 2018. (*Id.*) Throughout it all, Gilead made its own generic version of the drug. But generic competition reduced the total sales from Gilead's Viread from $514 million to about $50 million,[5] making TDF a

[5] As an aside, the AIDS Healthcare Foundation (AHF) urged that Gilead reduce its prices by 90%, including those for Truvada, which did not go off patent in December 2017. (*See* AHF (Oct. 17, 2017) *As Patent Expires, AHF Calls on Gilead for 90% Price Reduction on Tenofovir-based Drugs, Including Truvada*, <https://www.aidshealth.org/2017/10/patent-expires-

low-priced competitor to TAF, which was still under patent. In addition, Gilead's two compound drugs, Truvada and Atripla, remained under patent until October 2020, and they continued to enjoy robust sales through their respective expiration dates, even though TAF had been marketed successfully since 2017 and TDF was now generic. The later decline in sales of the two TDF drugs was solely a predictable response to the loss of patent protection when generics entered the market. Thus, Truvada sales dropped 88%, from $2.640 billion (2019) to $1.376 billion (2020) to $314 million (2021). Similarly, Atripla sales dropped 76% from $501 million (2019) to $307 million (2020). These figures do not represent a decline in use levels, given sales by generic companies, which TAF did not drive from the market.

The robust sales of TDF, Truvada, and Atriplia under patent after TAF was launched also shows that the Plaintiffs were wrong to allege that the TDF drugs could not survive the advent of the TAF products. They wrote:

> In order to unreasonably maximize its profits and maintain its stranglehold on tenofovir-based antiretroviral medications, Gilead intentionally devised a marketing scheme whereby it abandoned the immediate approval, manufacturer and sale of TAF in favor of the less effective, less safe TDF. Gilead knew that if it were to sell its safer TAF compound first, TDF would *never* be sold. Conversely, by selling TDF based drugs first, Gilead could reap the benefits of those sales, and then, later, market its safer TAF compound as a "product hop" or life cycle extension that would effectively monetize both drugs.

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ahf-calls-gilead-90-price-reduction-tenofovir-based-drugs-including-truvada/>) The 2020 data reflected the combination of patented and generic sales for the year. There was no reason why Gilead should have drop the prices of its protected compound drugs when TDF went off-patent, as AHF requested.

(Complaint at ¶ 61.)

This passage gets the chronology wrong. It falsely omits to mention that TDF had sold for three years before TAF came onto the scene in 2004, and it remained a strong seller so after TAF that the imaginary product hop never occurred. To make matters worse, the Plaintiffs overlook that the two drugs were introduced years apart by claiming that Gilead could have reversed priorities in 2004 when TDF was being developed. Without evidence, the Plaintiffs claim this 2004 announcement was all a ruse to "falsely claim that TAF was not different enough from TDF to warrant further development" now as part of a campaign led by Dr. Martin to get Gilead to develop *both* TDF and TAF in the desired sequence. (Complaint at ¶79.)

Exactly the opposite happened. Gilead correctly sequenced the approvals of the two drugs given that both BMS and Gilead *each* had once given up on TAF. Thus, in 2004, Gilead publicly announced that it was discontinuing its work on GS 7340 (what would become TAF), saying that the "company will continue to focus its research efforts on multiple targets for HIV, including protease inhibitors, non-nucleoside reverse transcriptase inhibitors, integrase inhibitors, and fusion inhibitors, as well as Hepatitis C virus (HCV) and diseases of the lymphatic system." (Gilead, *Gilead Discontinues Development of GS 9005 and GS 7340; Company Continues Commitment to Research Efforts in HIV,* (Oct. 21, 2004), <https://tinyurl.com/vx73z7y7>.)

Thus, Gilead's explanation for stopping work on TAF was that: "Gilead recently completed a Phase I/II viral dynamics study that did not demonstrate a sufficient antiviral response after administration of GS 9005. These results were consistent with the observed low oral bioavailability in an earlier Phase I study." (*Ibid.*) That account is flatly inconsistent with the Plaintiffs' false claim the research was halted because the test results for

TAF were *so good* that Gilead kept it under wraps for about 12 years. (*Gilead Tenofovir Cases*, *supra*, 98 Cal.App.5th at p. 919.)

Instead, the Court of Appeal noted Gilead "resumed work on TAF in 2011 and conducted a Phase III study to compare TDF- and TAF-based medications in 2013. That study, the Appellate Court concluded, meant that Gilead had conceded that its research provided "substantial evidence that TAF had less impact than TDF on renal function [and] bone metabolism." (*Id.* at p. 919 n.1.) Not so. That fact was not known in 2004, nor indeed before 2013. In addition, TAF was both better and safer than TDF only by ignoring TAF's use limitations and known side effects. No plaintiff whose injuries occurred before 2012 could have taken TAF to avoid kidney or bone losses.

For good reason, California courts require plaintiff pleading fraud to state "facts which show how, when, where, to whom, and by what means the representations were tendered." (*Stansfield v. Starkey* (1990) 220 Cal.App.3d 59, 73.) Similarly, Federal Rule of Civil Procedure 9(b) states: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."

Indeed, one exhaustive review study based on a meta-analysis of literature noted that TDF remains a key component of any regimen, notwithstanding the known risks of kidney and bone disease. (Bedimo et al., *Systematic review of renal and bone safety of the antiretroviral regimen efavirenz, emtricitabine, and tenofovir disoproxil fumarate in patients with HIV infection*, *HIV CLINICAL TRIALS* (Nov. 16, 2016) p. 246-266.) Gilead well understood the intensely competitive drug landscape when it introduced its new TAF line of products. Thus, it never sought to reap its supposed monopoly profits given the extensive market competition from other firms. "Apart from generic competition, Gilead must also face threats from other brands, as its competitors, ViiV Healthcare, Janssen, and Merck

& Co., are currently working on developing new HIV treatments to supplement their already strong portfolios." (Pharmaceutical Technology, *Gilead's Aggressive Promotion of its TAF-based HIV Portfolio Already Yielding Results*, GLOBALDATA (Mar. 23, 2017), <https://tinyurl.com/4acjasfv> (as of Oct. 25, 2024).) Gilead kept those prices low to meet competition even though its legal agreements with some potential generic competitors protected its key patents against generic competition until 2031-2032. (Fraiser Kansteiner, *Gilead settles 5 more Descovy patent feuds, pushing copycats to its PrEP successor out to 2031*, FIERCE PHARMA (Sept. 12, 2022), <https://tinyurl.com/2wh8anfa> (as of Oct. 25, 2024).) PrEP is pre-exposure prophylaxis. These sorts of "reverse payment" settlements raise complex antitrust issues that a rule of reason test controls. (*See F.T.C. v. Actavis, Inc*. (2013) 570 U.S. 136, 158.) Developing a large market base also allowed Gilead to, among other things, collect more long-term scientific data of safety and effectiveness,[6] which could help it maintain its position against current and future competitors.

According to Plaintiffs, one key element of Gilead's supposed grand strategy for the sequential marketing TDF and TAF was that wild-eyed claim the company could make a $5 billion profit even if it were held liable

[6] Note clinical trials have to be kept reasonably short so as to allow successful products to be marketed with enough remaining patent life. Hence, the search for adverse side effects often looks to surrogate end points to test product safety, and these can be flawed. (*See generally* FDA, *Surrogate Endpoint Resources for Drug and Biologic Development* (Jul. 18, 2018), <https://www.fda.gov/drugs/development-resources/surrogate-endpoint-resources-drug-and-biologic-development> (as of Oct. 25, 2024).) The longer that a product survives in the marketplace, the more likely that any latent long-term adverse side effects will be detected. Thus, an older drug may well do as well or better in its final years of patent product than earlier, because of the improved safety data.

to 25,000 people—"5,000 killed, 20,000 injured"—from various forms of kidney and bone ailments, just by pausing the sale of TAF products.

Those numbers are off by orders of magnitude. A conservative estimate of damages for one death or injury case is $1,000,000, which implies that 25,000 active cases translates into $25 billion in damage awards, for TAF whose total sales—from 2001 to 2023 were $65.279 billion. Add to that $25 billion, defense expenses for each individual case—remember there is no class action here—could easily reach 50 percent (or 12.5 billion) of the expected damage award, coupled with huge punitive damages for exposing a hideous plot, topped by criminal sanctions, and a huge loss of public and industry-wide goodwill. The Defendant goes under even if it could develop TDF for free. No one ever has adopted such an insane marketing strategy. And this lawsuit has taken its toll. As of October 2024, the market capitalization of Gilead is about $100.82 billion, which is in nominal dollars about two-thirds of its market cap in 2015.[7] It is sheer fantasy to assume that Gilead could contemplate this self-destructive strategy since both TDF and TAF have strong safety profiles, consistent with their long-term marketplace successes as both a proprietary and generic drug.

V. TDF v. TAF: Side by Side Medical Comparisons Show That Both Drugs Occupy Essential Market Niches.

One crucial, but erroneous element of the Plaintiffs' case is that TAF dominates TDF. But the publicly available medical evidence tells a different story on both safety and effectiveness, where some comparisons can be made among different drugs in the same class—here antivirals. In

[7] For the market capitalizations, (*see* <https://companiesmarketcap.com/gilead-sciences/marketcap/> (As of Oct. 25, 2024).)

general, neither drug ever has an absolute superiority in either dimension. Having two drugs increases the options for all patients, given that any single drug offers only incomplete coverage for the target population, which is why multiple entries promise additional benefits, up to the point where the benefits of adding a new drug are not worth the additional costs. "More safe, less dangerous," misstates the underlying medical realities.

To see why this is so with TDF and TAF, start with these two basic product descriptions.

> **Tenofovir disoproxil fumarate (Viread)**, also known as TDF, is a medication that's used as part of an antiretroviral (ARV) regimen for treating human immunodeficiency virus It's also a preferred medication[8]
>
> **Vemlidy (tenofovir alafenamide**), also known as TAF, is a first-choice medication for treating hepatitis B virus (HBV) for adults and children ages 6 years and older weighing at least 55 lbs.

(GoodRx, *Vemlidy tenofovir alafenamide—Used for Hepatitis B*, (Jun. 17, 2024) <https://www.goodrx.com/vemlidy/what-is> (as of Oct. 25, 2024).)

At no point does the official account of TDF refer to it as a second-class treatment, bound for oblivion. Instead, there are extensive guidelines for its dual uses, both in the treatment of HIV and hepatitis B viruses. It (not TAF) is described as a "first-choice medication" as part of an antiretroviral (ARV) for treating HIV. As of 2022, (when the product was generic) the full listing for the drug contains 41 separate citations for conditions that warrant its use, and those that do not. (*Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV*, CLINICAL INFO HIV.GOV (Sept. 21, 2022), <https://tinyurl.com/3pv7hk23> (as of Oct.

[8] For a similar account, *see* GoodRx, *Tenofovir Generic Viread*, (Jun. 17, 2024) <https://www.goodrx.com/tenofovir/what-is> (as of Oct. 25, 2024).

25, 2024).) In light of its preferred status, there are extensive guidelines about the use of antiretroviral agents in adults and adolescents with HIV as well as for HBV. TAF is also a first-choice medication for HBV, subject to restrictions on age and weight. But it is *not* listed as a first-class medication for all cases of HBV. In addition, TAF's use for HIV works only in combination with other drugs, which is not the case with TDF. The Plaintiffs' "safer, better trope" is refuted by these public descriptions. The overlap in use between the two drugs is only partial, which means that TAF could never have displaced TDF from every market niche no matter when it was introduced. Indeed, if there was some question of which drug should be brought to market first, the nod appears to go to TDF because of its wider spectrum of potential uses. But the addition of a second drug is prima facie welcome because of its different properties, which in turn yield different advantages for different subgroups. Thus, here is one comparative evaluation of the two drugs that reveals no strict dominance of one over the other:

> TDF is generally safe and well tolerated, but it can cause kidney problems and bone loss in some people. TAF has less effect on the kidneys and bones. On the other hand, TDF leads to lower cholesterol and triglyceride levels, which can lessen cardiovascular risk. TAF does not have the same beneficial effect on blood lipids, and it may be linked to greater weight gain.

(*TAF Versus TDF: What's the Difference?* POZ, <https://www.poz.com/basics/hiv-basics/taf-versus-tdf-difference> (as of Oct. 21, 2024).)

So not only is there no dominance in effectiveness of use of TAF over TDF, there is no dominance in their respective safety profiles. This is why both remain in wide use today, and why these warnings matter in helping physicians and patients in choosing the right course of treatment. There are thus two sources of uncertainty that wholly undermine the

Plaintiffs' implicit causal claims that everyone would prefer TAF to TDF. First, there is no reason to think that all these individuals presented in the same way and thus would want to make the same choices, given that nothing is more common than for individuals that suffer one disease, such as HIV, to also suffer from another, such as diabetes, which requires more nuanced treatment choices. Second, TAF does not reach all cases and thus could not have prevented all these bone and kidney cases. It is pure speculation, even with some very difficult spadework, to decide how effective any supposed treatment would have been for each of the named Plaintiffs, all of whom had in real time to respond to the warnings—whose adequacy was not challenged—in different ways. This individual causation means that individual claims cannot be disposed of in batches, given the unique paths taken in different places with different conditions at different times.

At this point, it is incorrect to allow the Plaintiffs to make either casual or frivolous fraud and concealment about actions that took place 20 years earlier, for which the Defendant gave the most common and sensible of reasons for not continuing a given line of research. There are many potential new drugs and any regime that, with the benefit of hindsight, commits a judicial determination of duty to require their commercialization is doomed to be wrong. In this regard, it makes no difference that the Plaintiffs purport to limit the creation of this duty to just one special subset of new chemical entities. The Court of Appeal showed no institutional awareness of how drug development works when it wrote in response to the charge that these novel duty of care cases are unmanageable. (*Gilead Tenofovir Cases*, *supra,* 98 Cal. App. 5th at p. 921.)

All of this is written only with the benefit of hindsight, without consideration of the enormous costs of investing in any new drug, which are always substantial. The foundational article on the costs of drug

development by Joseph A. DiMasi, Ronald Hansen and Henry Grabowski dates from 2003, whose basic analyses are still sound today. (*See* DiMasi et al., (2023) *The price of innovation: new estimates of drug development cost*s, 22 J. HEALTH ECON. 151, <https://tinyurl.com/mscntbnm> (as of Oct. 25, 2024).) The bottom line at the time of their research put the cost of a new chemical entity (NCE) at $403 million—in 2000 dollars, which given inflation of 82.1 percent is equivalent to $729 million today. The basic figure here reflects the costs of those drugs abandoned in development, which is a routine occurrence given the battery of biochemical analyses, animal studies, and the necessary clinical trials before any new drug is cleared for market. Most of these expenditures take place early in the development cycle, so that the actual financial outlay also must be grossed up to account for the cost of capital, which the authors estimate at about 11 percent per year, until the drug produces revenues only years later when it is released to the market. That high discount rate is attributed to the inherent riskiness of the venture. That correction then raises the price for a typical drug in 2000 to about $802 million dollars for a chemical entity, or about $1.45 billion today.

In light of these undisputed costs of drug development, the key blunder in the Court of Appeal's opinion is to speak of "Gilead's knowing and intentional *witholding* of such a treatment following its invention." (*Gilead Tenofovir Cases*, *supra,* 98 Cal. App. 5th at p. 921.) That most unfortunate phrasing makes it appear as if the "invention" of some new patented entity was ready for sale, with bottles of pills on the shelves ready for delivery. But what Gilead had for TAF in 2004 and 2011 was a prodrug compound that had yet to go through massive transformations and tests needed for it to reach the market. Given the huge number of eligible compounds to choose from and the difficulties in running these trials, hundreds of millions invested at that time could have led to one of the many

abandoned products of which DiMasi and his colleagues spoke. There is, moreover, nothing of use in the record to see the other products to which Gilead referred when it announced that it had abandoned further work on TAF to determine which products should be prioritized and why. No court, no jury, and not even the FDA, is in a position to decide, let alone second-guess, the investment decisions running into the billions of dollars which are needed to bring these drugs to market. This is a long way from mentioning to a house guest the broken faucet in *Rowland*.

Multiple criticisms pointed out how Gilead would necessarily retard new drug development by adding both costs and risk to any new project.[9] So the ultimate question is simple enough: Has the Plaintiffs' Complaint, as interpreted by the Court of Appeal, identified some subset of easy lawsuits that can be allowed to go forward without wrecking the entire process of drug innovation? "No!" Who will run the gauntlet of future clinical trials, FDA approvals, patent objections, and marketing difficulties if the decision below is affirmed? There are tradeoffs galore, not only in drugs' medicinal properties, but also in their stability, cost of storage, manufacture, administration, and a lot more. No one doubts that the framework for new drug development can be improved. But Plaintiffs' pie-in-the-sky proposal for so-called remediation is a death sentence, which must be lifted before it is too late.

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[9] *See* George Priest, *California's Negligence Tort Empowers Juries, Hurts Innovation*, (Feb. 14, 2024) Bloomberg News <https://news.bloomberglaw.com/us-law-week/californias-negligence-tort-empowers-juries-hurts-innovation> (as of Oct. 25, 2024) ("The appellate court's expansion of negligence in its ruling for the class members will likely reduce the number of new beneficial drugs on the market, increase their prices, and deter innovation in pharmaceuticals and other products."); *see also* Richard A. Epstein, *How Legal adventurism stifles medical innovation*, (Feb. 16, 2024) ORANGE COUNTY REGISTER, <https://tinyurl.com/bdhjjmw6 (as of Oct. 25, 2024).

CONCLUSION

The decision of the Court of Appeal should be reversed and the Plaintiffs' Complaint dismissed with prejudice.

Respectfully submitted,

/s/ Richard A. Epstein

Richard A. Epstein
16 Thomas Place
Norwalk, CT 06853
Counsel for *Amicus Curiae*

Dated: November 1, 2024

CERTIFICATE OF WORD COUNT

Pursuant to California Rules of Court, rule 8.504, I certify that the total word count of this amici curiae brief in support of Petitioners, excluding covers, table of contents, table of authorities, and certificate of compliance, is 12,539 using Microsoft Word.

By: */s/ Richard A. Epstein*

Richard A. Epstein
16 Thomas Place
Norwalk, CT 06853
Counsel for *Amicus Curiae*

Dated: November 1, 2024

PROOF OF SERVICE

Gilead Tenofovir Cases

Case No. S283862

STATE OF CONNECTICUT, COUNTY OF FAIRFIELD

At the time of service, I was over 18 years of age and not a party to this action. I am employed in the County of Fairfield, State of Connecticut. My business address is 16 Thomas Place, Norwalk, Connecticut 06853

On November 1, 2024, I served true copies of the following document(s) described as **AMICUS BRIEF IN SUPPORT OF PETITIONER, GILEAD SCIENCES, INC.**, on the interested parties in this action as follows:

SEE ATTACHED SERVICE LIST

BY ELECTRONIC SERVICE: I electronically filed the document(s) with the Clerk of the Court by using the TrueFiling system. Participants in the case who are registered users will be served by the TrueFiling system. Participants in the case who are not registered users will be served by mail or by other means permitted by the court rules. I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on November 1, 2024, in Norwalk, Connecticut.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on November 1, 2024, in Norwalk, Connecticut.

By: */s/ Richard A. Epstein*
Richard A. Epstein

SERVICE LIST

Gilead Sciences, Inc. v. The Superior Court of California, County of San Francisco (S283862)

Elizabeth Bixby, Esq. ORRICK, HERRINGTON & SUTCLIFFE LLP 355 S. Grand Avenue, Suite 2700 Los Angeles, CA 90071 Telephone: (213) 629-2020 Email: ebixby@orrick.com	**Attorneys for Petitioner** Gilead Sciences, Inc
E. Joshua Rosenkranz, Esq. Andrew Silverman, Esq. Naomi Scotten, Esq. Siobhan Atkins, Esq. Emily Villano, Esq. ORRICK, HERRINGTON & SUTCLIFFE LLP 51 West 52nd Street New York, NY 10019 Telephone: (212) 506-3727 Email: jrosenkranz@orrick.com asilverman@orrick.com nscotten@orrick.com satkins@orrick.com evillano@orrick.com	**Attorneys for Petitioner** Gilead Sciences, Inc
Hon. Andrew Y.S. Cheng SAN FRANCISCO COUNTY SUPERIOR COURT Complex Civil Litigation, Dept. 613 400 McAllister Street San Francisco, CA 94102	**Respondent (Via U.S. Mail Only)** Superior Court of San Francisco County
M. Elizabeth Graham, Esq. GRANT & EISENHOFFER P.A. 201 Mission Street, Suite 1200 San Francisco, CA 94105 Telephone: (415) 229-9720 Email: egraham@gelaw.com	**Attorneys for Plaintiffs and Real Parties in Interest**
William A. Kershaw, Esq. KERSHAW, TALLEY, BARLOW PC 401Watt Avenue Sacramento, CA 95846 Telephone: (916) 779-7000 Email: bill@ktblegal.com	**Attorneys for Plaintiffs and Real Parties in Interest**
Robert K. Jenner, Esq. JENNER LAW, P.C. 3600 Clipper Mill Road, Suite 240 Baltimore, MD 21211 Telephone: (410) 413-2155 Email: rjenner@jennerlawfirm.com	**Attorneys for Plaintiffs and Real Parties in Interest**

Amy Eskin, Esq. SCHNEIDER WALLACE COTTRELL KONECKY LLP 2000 Powell Street, Suite 1400 Emeryville, CA 94608 Telephone: (510) 740-2936 Email: aeskin@schneiderwallace.com	**Attorneys for Plaintiffs and Real Parties in Interest**
Myron Moskovitz, Esq. MOSKOVITZ APPELLATE TEAM 90 Crocker Avenue Oakland, CA 94611 Telephone: (510) 384-0354 Email: myronmoskovitz@gmail.com	**Attorneys for Plaintiffs and Real Parties in Interest**
Jeffrey Lawrence, Esq. THE LAWRENCE LAW FIRM Levi's Plaza 1160 Battery Street East, Suite 100 San Francisco, CA 94111 Telephone: (415) 685-5030 Email: jeffreyl@jlawrencelaw.com	**Attorneys for Plaintiffs and Real Parties in Interest**
Seth A. Katz, Esq. BURG SIMPSON ELDREDGE HERSH & JARDINE, P.C. 40 Inverness Drive East Englewood, CO 80112 Telephone: (303) 792-5595 Email: skatz@burgsimpson.com	**Attorneys for Plaintiffs and Real Parties in Interest**
Geoffrey A. Manne Kristian Stout Jeremy Kidd INTERNATIONAL CENTER FOR LAW & ECONOMICS 1104 NW 15th Avenue, Suite 300 Portland, OR 97209 Telephone: (503) 770-0076 Email: kstout@laweconcenter.org	**Amicus Curiae** International Center for Law & Economics
John M. Potter, Esq. QUINN EMANUEL URQUHART & SULLIVAN, LLP 50 California Street, 22nd Floor San Francisco, CA 94111 Telephone: (415) 875-6600 Email: johnpotter@quinnemanuel.com	**Attorneys for Amici Curiae** ALLvanza, Global Coalition on Aging, HIV and Hepatitis Policy Institute, Liver Coalition of San Diego, National Minority Quality Forum, Partnership to Fight Chronic Disease, and Phill Wilson
Ashley M. Simonsen, Esq. Alice L. Phillips, Esq.	**Attorneys for Amici Curiae** Pharmaceutical Research and

COVINGTON & BURLING LLP 1999 Avenue of the Stars Los Angeles, CA 90067 Telephone: (424) 332-4782 Email: asimonsen@cov.com aphillips@cov.com	Manufacturers of America, Advanced Medical Technology Association, Biotechnology Innovation Organization, and the Medical Device Manufacturers Association
Michael X. Imbroscio, Esq. Emily Ullman, Esq. Cara Souto, Esq. **COVINGTON & BURLING LLP** 850 Tenth Street NW Washington, DC 20001 Telephone: (202) 662-6000 Email: mimbroscio@cov.com eullman@cov.com csouto@cov.com	**Attorneys for Amici Curiae** Pharmaceutical Research and Manufacturers of America, Advanced Medical Technology Association, Biotechnology Innovation Organization, and the Medical Device Manufacturers Association
Gregory L. Halperin, Esq. **COVINGTON & BURLING LLP** 620 Eighth Avenue New York, NY 10018 Telephone: (212) 841-1000 Email: ghalperin@cov.com	**Attorneys for Amici Curiae** Pharmaceutical Research and Manufacturers of America, Advanced Medical Technology Association, Biotechnology Innovation Organization, and the Medical Device Manufacturers Association
Paul A. Alarcon, Esq. **BOWMAN AND BROOKE LLP** 600 Anton Boulevard, Suite 650 Costa Mesa, CA 92626 Telephone: (310) 380-6500 Email: paul.alarcon@bowmanandbrooke.com	**Attorneys for Amicus Curiae** The Product Liability Advisory Council, Inc.
Charles C. Lifland, Esq. Sabrina H. Strong, Esq. Jeffrey L. Fisher, Esq. Jason Zarrow, Esq. **O'MELVENY & MYERS LLP** 400 South Hope Street, 18th Floor Los Angeles, CA 90071 Telephone: (213) 430-6000 Email: clifland@omm.com	**Attorneys for Amici Curiae** Amgen, Inc., Bayer U.S. LLC, Biogen Inc., Bristol-Myers Squibb Company, Edwards Lifesciences Corporation, Genentech, Inc., Glaukos Corporation, Hyundai Motor America, Johnson & Johnson, Inc., Kenvue Inc., Kia America, Inc., Novartis Pharmaceuticals Corporation, Organon & Co., Roche

	Molecular Systems, Inc., Sanofi US, Takeda Pharmaceuticals U.S.A., Inc., and Zimmer Biomet Holdings, Inc.; BioMarin Pharmaceutical, Inc. and Vertex Pharmaceuticals, Inc