The Perils of Pharmaceutical Innovation: The Surreal Tale of TDF and TAF

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ABSTRACT

This Article intervenes to correct a major error in the law of products liability that is working its way through the California court system. In the *Gilead Tenofovir Cases* now before the California Supreme Court, the Court of Appeals allowed the case to reach a jury on the theory that in 2004, Gilead did not develop a new product, TAF, in order to protect its monopoly position in its earlier product, TDF, which launched with great success in 2001. Gilead had adequately warned that TDF in a small number of cases produced adverse effects to kidneys and bone. The new theory stated falsely that it was clear that TAF was both safer and more efficient than TDF and would drive it off the market with an early release. But both TDF and TAF remain top-rated drugs in wide use with overlapping but distinct advantages, as they compete with each other and with other antivirals from other companies. A close look at the antitrust, patent, and tort theories underlying the plaintiffs' claims highlights the implausibility of the claims and the deep conceptual errors in the creation of this new and dangerous tort duty—including its supposed reliance on Section 1714 of the state's Civil Code, which has never been applied to product liability cases or to mandate an untethered tort duty to investigate new drugs that the patent holder did not at the time think worthy of further research and development. Allegations of product hopping, fraud, and negligence all wither under scrutiny. To allow this case to proceed to trial creates the prospect that highly successful drugs that meet all FDA standards can produce catastrophic losses for the companies that produce them, which works against the interests of patients and health care providers alike.

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I. INTRODUCTION

The subtitle to this Article joins together two elements: legal issues that should be straightforward, and medical issues that are often not. The question of pharmaceutical innovation is on everyone's lips today. Like the rule of law, everyone is for it and no one is against it. So the policy debate usually starts and ends with a judgment that this or that policy initiative either advances or retards innovation. That vital question of *means* asks whether the patent system works to stimulate innovation by giving inventors the exclusive rights to their inventions for some limited period of time,[2] or whether that exclusion operates as a barrier to entry by other firms that can introduce competition in the marketplace by creating generic substitutes.

Many of these issues are brought front and center in a major lawsuit now before the California Supreme Court. The suit depends on a fusion of these tort and medical issues, and holds the possibility of expanding exponentially the scope of manufacturer liability for the sale and promotion of pharmaceutical drugs. That outcome is possible because the Appellate Court in *Gilead Tenofovir Cases v. Superior Court—Plaintiffs in JCCP Np. 5043, RPI*[3] has adopted a bold theory of liability that held, in essence, that it was not necessary for the plaintiff in a product liability case to show that a challenged product was defective in terms of its fabrication, design, or warnings. Instead, it applied what it termed the ordinary principles of negligence, as enunciated chiefly in the case of *Rowland v. Christian,*[4] insofar as it dealt with Section 1714 of the California Code to impose huge liabilities, even if the product in question was safe when made and its marketing met all applicable FDA standards relating to warnings and fabrication.

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2 *See* Patent Act. 35 U.S.C. §§ 101-103.

3 98 Cal. App. 5th 911 (2024), 317 Cal. Rptr. 3d 133, cert. granted, ---P.3d. ---- 2024 WL 1919710 (Mem).

4 443 P.2d 561 (Cal. 1968).

The issues that have to be discussed concern two distinct drugs—tenofovir disoproxil fumarate, (TDF) which was introduced first in 2001, and tenofovir alafenamide (TAF), which first reached the market in 2014. The gist of the plaintiffs' case is that Gilead, the defendant pharmaceutical company, strategically kept TAF off the market in order to reap excessive profits from TDF. The story necessarily requires that Gilead sought to obtain a supercompetitive return on both drugs by its scheme. It follows that these key questions must be addressed:

• Did Gilead possess some monopoly power that allowed it to "product hop" from TDF to TAF so as to gain monopoly profits from both?

• Did Gilead deceive the public when it announced negative results for its tests on TAF in 2004?

• Is it true that TAF was a known superior product that was kept off the market until 2015 because an earlier launch would have driven the sales of TDF to zero?

• Could Gilead profit from deliberately concealing the defects of TDF?

• Do the side-by-side comparisons of TDF and TAF reveal the unquestioned dominance of TAF?

• Do the California cases, starting with *Rowland v. Christian*, support the creation by judicial action of a new duty for companies to develop new drugs that are said to be safer and superior to early drugs, when it turns out that both drugs remain in use as overlapping, first-line treatments for various viral disorders?

None of these questions were systematically addressed by either of the principal briefs in this case.[5] Instead of offering a systematic account of how the tort law operates and how it interacts with the system of direct regulation under the FDA, the two briefs offer warring quotations on the scope of foreseeability in tort law, but without situating these remarks in the factual context of the individual cases. That last task is strictly necessary. The recent decisions in the California Supreme Court showed a sensible division of responsibility according to which, as an accurate first approximation, the duty to prevent harm caused by either other individuals or natural sources falls—if it falls on anyone—solely on those individuals who have direct and immediate control over a particular situation, where it is possible to identify what steps are needed and why. There

[5] See Petitioner's [Defendant] Opening Brief on the Merits (7/15/2024)

exist no cases in which a remote actor, exercising its business judgment on what products should be developed and why, has been held responsible in tort for its actions which are thereafter followed by extensive oversight over the same products by first the FDA, and then by hospitals, physicians, and industry groups. The point is doubly true when the plaintiffs make explicit predictions about the superiority or TAF over TDR that are falsified by undisputed evidence on the public record—evidence showing that both TAF and TDR have competed successfully with each other and with other antiviral drugs marketed by sophisticated rivals.

The flaws in plaintiffs' approach is highlighted by a novel hypothetical, introduced in oral argument in the Court of Appeals, 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 a delayed launch after receiving FDA approval in 2015. The plaintiffs claimed that this gap resulted in some 25,000 deaths and injuries from bone and kidney disease that could have been avoided by an earlier launch of that superior product. That number is out of a base of millions of users for both drugs which have remained in the market, in part because the actual rate of harm attributed to kidney difficulties and bone damage for TDF users suffering from either condition is vanishingly small, affecting 0.002% and 0.11% of the millions of patients, respectively, per year. Against this impressive safety record, the plaintiffs' substantive claim was that the defendant, Gilead, owed a duty of immediate development on the factual ground that TAF had both stronger curative properties and fewer side effects. The only reason to resist promptly developing, promoting, and selling TAF, the plaintiffs' argument goes, was to milk monopoly profits from the older TDF product before "product hopping" customers over to TAF, so as to continue its monopoly position into a second generation. The Court of Appeals held that, even if tort liability for products typically depended on a showing of a defective drug, liability could also be established by showing that Gilead was negligent—or worse, willful and fraudulent—in 2004 by concealing the truth from the public, solely to milk illicit profits from TDF until TAF hit the market in 2015.

In this Article, I shall take up these questions, starting with an analysis of the good-versus-evil account of drug development that the plaintiffs persuaded the Court of Appeals to adopt to let this case reach the jury. Thereafter, I shall offer a sharp critique of the legal principles used by that court to create the common law duty to develop TAF. The analysis of TDF v. TAF has

implications to all other instances of drug innovation. Throughout I present arguments that differ radically from those that the defendants offered in oral argument at the Court of Appeals.

The following section of the Article, Part II, explains the severe factual deficiencies with the plaintiffs' case—deficiencies that should have resulted in dismissal on the pleadings given the absence of any genuine dispute of fact, or alternatively, by summary judgment for the defendants, rather than allowing it to reach a jury. It gives a close analysis of the key events in the cycles for marketing and using both TDF and TAF. It reveals a complex picture that falsifies at every turn the plaintiffs' narrative that Gilead shoved aside a superior product in order to market an inferior one solely for financial gain. Once the full medical record is understood, lawsuits of this sort should be stopped at the pleading stage as simply implausible before the massive costs and distraction of litigation impairs further pharmaceutical development.

The subsequent section, Part III, explains how, even crediting the plausibility of plaintiffs' claims, the duty of care asserted sits at radical disjuncture from legal duties cognizable under California tort law. The duty recognized by the Court of Appeals is so divergent from precedent because it ignores the most basic facts and distinctions found in all the canonical cases. Having no basis either in fact or in law, the Court of Appeals' decision in the *Gilead Tenofovir* cases threatens to impose severe harms on medical innovation and the welfare of patients across the globe.

II. WHY PLAINTIFFS' CASE IS LEGALLY IMPLAUSIBLE AND FACTUALLY UNTENABLE

A. The Complaint

The gist of the plaintiffs' case is stated in the opening paragraph of their complaint:[6]

> Gilead is a California pharmaceutical company. In 1991, Gilead acquired the exclusive rights to develop, manufacture, distribute and sell an antiviral compound called tenofovir for the treatment of HIV/AIDs. Beginning in 2001, Gilead manufactured and sold a prodrug[7] form of tenofovir called tenofovir disoproxil

[6] Complaint, *Gilead Tenofovir Cases*, Superior Court for the State of California, CJC-19-005043, Jan. 30, 2020, ¶¶ 1–2.

[7] Note that a prodrug is defined 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.

The American Heritage® Dictionary of the English Language, 5th Edition.

> fumarate or TDF. Unbeknownst to Plaintiffs and the general public, Gilead had also developed another prodrug form of tenofovir called tenofovir alafenamide fumarate or TAF, which it knew to be more efficacious and less toxic to kidneys and bones than TDF. Despite knowing of the disparity between TDF and TAF, Gilead withheld development of its safer product, TAF, to artificially and unreasonably maximize profits on its TDF-based medications first. Despite the fact that Gilead owed its patients to distribute the safest drug available, it 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" or lifecycle extension that would effectively monetize both drugs.
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> It was only in response to market pressures—not concern for patient health and safety—that Gilead eventually applied for FDA approval for the first time in or about 2015, after maintaining an exclusive and extremely profitable monopoly on TDF for some 15 years.

The theory that was announced in the complaint received its "hypothetical" endorsement in the appellate court in this exchange which the plaintiffs highlight in their own brief:[8]

> 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 back with a hard estimate, 25,000 people would be injured or killed— 5,000 killed, 20,000 injured.
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> 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.*
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> "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."

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Gilead's counsel responded: "So, yes, that is correct." (OA.62:10-19). Correct is indeed the right answer, but it was expressed without looking at the factual record, which

[8] Plaintiff's Answering Brief on the Merits, at 42-43, filed 8/14/2024. WILL SEND OVER.

shows that every facet of this story is fabricated. To understand why, we must take a closer look at the differences between the drugs, explored below in Part II.B, as well as plaintiffs' monopolization argument, explored below in Part II.C.

B. TDF v. TAF: Side-by-Side Medical Comparisons

First, it is imperative to examine the overall record of both drugs, just as the FDA needed to (a matter that should itself have raised strong preemption defenses that were not discussed in the case).[9] The comparison of two drugs that are roughly within the same family is always difficult. The two relative dimensions are safety and effectiveness, but each of these calculations is hard to make. In dealing with the former issue, the challenge is to identify and, if possible, quantify the magnitude of any given class of risks. So long as two products, like TDF and TAF, are chemically distinct, the side effects associated with one product could be very different from those associated with the other. The body has many organs and countless different processes, such that it is highly unlikely that any two powerful treatments, even in the same class, will generate the same biological responses, either positive or negative, across their overlapping target populations. The question of effectiveness is also not uniform, as some individuals can tolerate strong medicines that others cannot. Hence, it is common to vary dosages of a given chemical or to switch to a different drug in the same class for some but not all of a target population. The one clear conclusion is that having just a single drug risks incomplete coverage of the target population, which is why new entries in the class promise additional benefits, and will continue to be introduced until the remaining gains are not worth the additional costs.

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

> **Tenofovir disoproxil fumarate**, also known as TDF, (Viread) is a first-choice medication that's used as part of an antiretroviral (ARV) regimen for treating human immunodeficiency virus (HIV) infections. It's also a preferred medication used for treating hepatitis B virus (HBV).[10]
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> 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.[11]

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[9] See, for the basic framework, Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947), which addresses theory of conflict, field and frustration as headings for preemption, all of which could be applicable here.

[10] For a similar account see GOODRx Tenofovir Generic Viread, available at https://www.goodrx.com/tenofovir/what-is.

[11] Vemlidy tenofovir alafenamide—Used for Hepatitis B, available at https://www.goodrx.com/vemlidy/what-is.

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 virus. Its description as a "first-choice medication" as of September 2022, which, when the product was generic, contains 41 separate mentions for the conditions that warrant the use of the drug and those that do not, suggests that no single product could ever hold a monopoly position.[12] In light of their critical role, there are extensive guidelines about the use of antiretroviral agents in adults and adolescents with HIV as well as 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, it can be used for HIV but only in combination with other drugs, which is not the case with TDF. The overlap in use between the two drugs therefore is not complete, which means that TAF could never have displaced TDF from every market niche. Indeed, if there was some question of which drug should have been brought to market first, the nod would appear to go to TDF because of its wider spectrum of potential uses. But the addition of a second drug like TAF is prima facie welcome because of its different properties, which in turn yield different advantages for different population subgroups. Thus, one comparative evaluation of the two drugs 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.[13]

It should also be recalled that the distribution of TDF was complex, with warnings about the well-known risks to kidneys and bones, so that the plaintiffs could not have brought a breach of duty to warn case.[14] In addition, any suit for individual damages—remember, this is not a class

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[12] Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV Clinical Info HIVGOV, available at https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/what-start-initial-combination. Updated as of 09/12/2024.

[13] *TAF Versus TDF: What's the Difference?* POZ, https://www.poz.com/basics/hiv-basics/taf-versus-tdf-difference. (as of January 19, 2025).

[14] For discussion, see L. Chan et al, Potential Kidney Toxicity from the Antiviral Drug Tenofovir: New Indications, New Formulations, and a New Prodrug, Current Opinion in Nephrology and Hypertension, https://journals.lww.com/co-

action, but an aggregation of individual cases—has to fail given this high level of variation. T wo sources of uncertainty lurk in all the 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 it is common for individuals who suffer one disease, such as HIV, to also suffer from another, for example diabetes, which make treatment choices complex and individualized. And second, TAF does not reach all cases and thus could not have prevented all these bone and kidney cases. So 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 could have responded to the warnings—whose adequacy was not challenged—in their own personal ways.

C. The Flawed Monopolization Argument

As a rhetorical matter, it is easy to be aghast at the tragic outcome foretold by Gilead's affirmative response to the hypothetical posed in the complaint in Part II.A, above. But the hard question is whether there is *any* chance this monopolization hypothetical, which the plaintiffs urge multiple times in their complaint,[15] can be true in any real- world setting. The answer here, emphatically, is *no*. The record in this case contradicts every assumption raised by both the plaintiffs' complaint and the related judicial hypothetical. And the conditions that establish the errors here are so systematically ingrained that it is hard to imagine any conceivable pharmaceutical setting in which these extreme allegations could possibly be true. The reason to reject this theory is that its basic assumptions are universally and tragically wrong, so that it is unwise to allow legal exercise to purport to establish what can never be so. As such, it fails the basic test announced in both *Bell Atlantic Corp. v. Twombly*[16] and *Ashcroft v. Iqbal*.[17]

The first point here is a key terminological one. The plaintiffs write as if Gilead enjoyed "an exclusive and extremely profitable monopoly on TDF (marketed as Viread) for some 15 years." [18] Their point is that Gilead was able to exploit that monopoly power by "product hopping."

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nephrolhypertens/abstract/2018/03000/potential_kidney_toxicity_from_the_antiviral_drug.8.aspx (2018), also available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6103211/

[15] See, note 10, supra.

[16] 550 U.S 544 (2007). While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the "grounds" of his "entitle[ment] to relief" requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. *Id* at . (internal citations omitted).

[17] 566 U.S. 662 (2009) (similar).

[18] Plaintiff's Complaint. ¶ 2. The charge of monopoly pricing is also made in ¶ 78, ¶90, ¶ 95, ¶ 100 & ¶107, note 7.

Wrong. The patent law does not give any patentee a monopoly over any product market, let alone a monopoly treating either HIV or Hepatitis B, the drugs for which TDF is targeted. Rather, it gives the firm the exclusive right to sell that patented compound. The sales of the drug may be highly profitable because of the size of the market and efficacy of the drug. Patent law does not give any patentee an economic monopoly over some relevant market for a given product (e.g., statins) because it sells any patented product, so long as rival drugs exist in the market. It is even less credible to say that a patented drug confers an exclusive right to develop new products treating either HIV or Hepatitis B, the viruses to which TDF is targeted. At all times, rival drugs from other manufacturers challenged TDF, whether or not TAF was also on the market.[19] Profitable drugs do not generate illicit monopoly profits. Yet apart from their unsubstantiated claim of monopoly power, the plaintiffs offer no discussion of the relevant market conditions.

The most evident defect of the complaint lies in its use of the evocative term "product hop," which makes it appear as though Gilead could shift from one product to another in the blink of an eye. A recent Federal Trade Commission Report on Pharmaceutical Product Hopping (2022) explains why the extension is in inappropriate:

> Product hopping is a strategy where a brand-name pharmaceutical company seeks to shift demand from a brand-name drug that faces generic competition to 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.[20]

Both TDF and TAF are first-in-class drugs, and neither represents an insignificant change from the other. The supposed shift cannot possibly take place. The entire FTC report stresses how small modifications in brand-name drugs can stifle the entry of generic competition. At no point does that report ever refer 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, and Suboxone), all of which involve moving from one product to a different product with insignificant differences in therapeutic effect, solely

[19] See *Illinois Tool Works, Inc. v. Independent Ink*., 547 U.S. 28 (2006) (denying that a patent gives monopoly power to support a tie-in case).

[20] Federal Trade Commission—Report of Product Hopping available at https://www.ftc.gov/system/files/ftc_gov/pdf/p223900reportpharmaceuticalproducthoppingoct2022.pdf.

to avoid generic competition for basically the same drug. The so-called Orange Book[21] also contains a list of "reference standards" that generics seeking to file an Abbreviated New Drug Application (ANDA) must serve, as the name implies, as the reference for the new drug.[22] That standard can be withdrawn only for a determination that the drug no longer meets the standards of safety and effectiveness, which was never an issue with TDF. So long as other companies can enter the generic market, they can undercut any supposed monopoly power. Given these powerful institutional constraints, the imaginary product switcheroo could never have been executed. Moreover, Gilead was helpless to prevent the entry of rival drugs by other producers of antiviral drugs that compete with both TDF and TAF. And finally, plaintiffs' theory suffers from a fatal internal contradiction. If, as the plaintiffs allege, TAF truly is a superior chemical compound to TDF, then TAF cannot be a new, adjacent product that offers only "little or no apparent medical benefit," as required for product hopping. The plaintiffs must get their stories straight: Is TAF truly superior, or is merely a mechanism for a "product hop"?

It is one measure of the desperation of the plaintiffs that they have zero evidence of a supposed monopoly position for these antiviral drugs. The plaintiffs do observe that in 2006 Gilead expanded its supposed monopoly position by releasing one of its several combination drugs, Atripla.[23] But there is no evidence at all that the introduction of the second product confers any more of a monopoly power than does the marketing of the first, given that Atripla both works in competition against TDF and from the same array of antiviral rivals to TDF. The release of a compound product is utterly unremarkable, and there is no hint anywhere in the record that these actions provoked any antitrust response, either by federal or state governments or private parties, which undercuts the plaintiffs' supposed monopolization argument.

A further fragmentary claim of monopoly stems from the fact that Gilead obtained the exclusive rights to manufacture the TDF class of compounds from Bristol-Myers (later merged with Squibb to make BMS). Nonetheless, that assertion is similarly empty because it rests on the observation that Bristol-Myers sold its rights to the TDF class of compounds to Gilead because Bristol-Myers had lost confidence that TAF had commercial value.[24] But far from being improper,

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[21] Formally called *Approved Drug Products With Therapeutic Equivalence Evaluation* available at https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.
[22] *Id.* at 1.4 Reference Listed Drug and Reference Standard.
[23] Complaint ¶90.
[24] Complaint ¶¶31-34.

that transfer represents the efficient operation of the pharmaceutical marketplace. The company that valued the product's commercial prospects more purchased the product from the company that valued them less, and then signed on the physician at Bristol-Myers (in this instance, Dr. John C. Martin) who had championed its potential value. The plaintiffs then made an equally unsound allegation that Gilead had entered into "anticompetitive" deals with a wide range of companies, including Bristol-Myers to develop other compound products, including Atripla. The error is that developing other compound products has the effect of expanding the number of products in the market, which enhances competition rather than suppresses it. The following Table is most revealing:

Table 1 – Gilead Tenofovir Revenues in United States by Product, 2012 through 2023[25]

One key element is the transition that takes place when TAF products enter the market in 2015, and TDF goes generic in late 2017 and early 2018. In December 2017, TDF had estimated market revenues of $734.4 million .[26] 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 15, 2018.[27] Throughout it all, Gilead made its own generic version of the drug. But the effect of the generic competition was to reduce the total sales from Viread from $514 million to about $50 million.[28] At this point it turns out that generic TDF became a low-

[25] Available at https://drive.google.com/file/d/18gKhhxgsqCtHjlVsNQrdUyXMNvHsi_el/view?usp=drive_web.

[26] Aurobindo Receives FDA Approval for Tenofovir Disoproxil Fumarate Tablets, January 26, 2018, available at https://www.aurobindousa.com/news/aurobindo-receives-fda-approval-for-tenofovir-disoproxil-fumarate-tablets/

[27] *Id.*

[28] As an aside the Aids Healthcare Foundation (AHF) urged that Gilead reduce its prices by 90 percent, including those for Truvada, which did not go off patent in December 2017. *See* AHF, *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-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. Similarly Atripla sales dropped 76%: from $501M (2019) to

priced competitor to TAF, which necessarily would have reduced TAF's sales, even if Gilead had entirely removed the original TDF from the market, which it did not. In addition, the two compound drugs, Truvada and Atripla, remained on 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. The decline in sales of the two TDF drugs was solely a predictable response to the loss of patent protection, at which point generics, including those sold by TEVA, drove the prices down. 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) to $121 million (2021). These figures do not represent a decline in use levels given the substantial shares by other generic companies, which speaks to the continued value of these drugs after TAF was on the market. Clearly, TAF did not drive them from the market.

Similarly, the robust sales of Truvada and Atripla while still under patent even after TAF was launched also shows that the plaintiffs were flatly wrong when they asserted that the TDF drugs could not survive the advent of the TAF products. Plaintiffs wrote:[29]

> 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, manufacture 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.

This passage from the plaintiffs' complaint fails to acknowledge that TDF sales thrived well after TAF hit the market. Plaintiffs never ruled out the risky possibility that the supposedly inferior TDF could fail in the marketplace because a rival product from a third supplier could have been better than TDF but worse than TAF, which would have caused Gilead stiff financial losses with both products. None of that risk happens if, as turned out to be the case, TDF was a strong contender in its own right, such that Gilead had no intention of taking it, or any of its distinct variants, off the market once TAF was put on the market—a self-defeating move that would hurt

$307M (2020) to $121M (2021). There was no reason why Gilead should have drop the prices of its protected compound drugs when TDF went off-patent as AHF urged.

[29] Complaint, ¶ 62 (emphasis added).

both itself and its customers. The delay in entry came solely from the fact that Bristol-Myers and Gilead *each* had once given up on the drug. Gilead changed course because its research indicated that TAF was a potential winner, which is exactly what it should have done.

One further piece of evidence that Gilead did not have any market power is that in 2015, when it introduced its new TAF line of products, the pricing of TAF did not reflect its supposed monopoly position, given extensive market competition from other firms. Accordingly, it was reported that:

> "Gilead chose to price Genvoya and Odefsey [its new brands] slightly lower than Stribild and Complera [its older TDF variants] in the US to encourage switching onto the TAF-based regimens, which are under patent protection for the foreseeable future. Apart from generic competition, the company 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."[30]

The situation here is instructive. Owing to (legal) deals with some of its potential generic competitors, Gilead will hold its key patents against generic competition until 2031-2032.[31] Yet it chose to keep its prices low given the other competition, which could only increase over the patent life. It was important, therefore, for Gilead to establish a large market base. Doing so would, among other things, allow it to collect more long-term scientific data of safety and effectiveness,[32] which could help it maintain its position against competitors determined to boost their effectiveness and safety profiles.

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[30] Global Data Healthcare, Comment, *Gilead's Aggressive Promotion of its TAF-based HIV Portfolio Already Yielding Results*, PHARMACEUTICAL TECHNOLOGY (March 23, 2017), https://www.pharmaceutical-technology.com/comment/commentgileads-aggressive-promotion-of-its-taf-based-hiv-portfolio-already-yielding-results-5771127/.

[31] Fraiser Kansteiner, Gilead settles 5 more Descovy patent feuds, ushing copycats to its PrEP successor out to 2031, Fierce Pharma Sept. 12, 2022, available at https://www.fiercepharma.com/pharma/gilead-settles-descovy-patent-feuds-five-more-generics-makers-pushing-copycats-its-prep. PrEP equals pre-exposure prophylaxis. Settlements of this sort raise complex antitrust issues. *See FTC v Actavis*, 570 U.S. 136 (2013), which announced a rule of reason test for these "reverse payment" settlements whereby an incumbent pays one or more generics to stay out of certain markets for a limited period of time, which can be attacked as collusive agreements on the one hand, or regarded as settlement of uncertain patent questions on the other. Dealing with that issue is outside the scope of this Article.

[32] One avoidable weakness of all clinical trials is that they 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 (7/18/2018), available at https://www.fda.gov/drugs/development-resources/surrogate-endpoint-resources-drug-and-biologic-development. The more years that a product survives in the marketplace the more likely it could detect some long-term adverse side effects. Thus an older drug may well do as well or better in its final years of patent product than earlier years, because of the improved safety data.

Speaking more generally, the plaintiffs cannot offer any credible story about how Gilead could flip its supposed monopoly power seamlessly from TDF to TAF when both remained on the market, TDF as a generic and TAF as a proprietary drug. Indeed, the arguments in plaintiffs' complaint bear some vague resemblance to tactics that are often raised in connection with efforts to adopt the opposite strategy—that of predatory pricing in a (futile) effort to drive out competitors in order to establish thereafter a monopoly position. But that strategy universally fails unless there is some external barrier to entry after the predatory period so that the necessary recoupment could follow.[33] The artificially low prices (i.e., often below variable costs) for goods and services induce a huge surge of demand that results in large immediate losses to the supposed predator that are hard, indeed impossible, to recoup at some future time, given that current competitors need only remain off the market (or buy the rivals product at below market prices), only to jump back in under a price umbrella raised by the (supposed) monopolist once the predator (or group of predators) abandon their plan so that recoupment with monopoly prices is no longer possible.[34] The only proven ways to gain monopoly power are to obtain formal entry restrictions or to cartelize the market with other producers in the same space, neither of which was done with either of the TDF and TAF products. The notion that any unilateral pricing strategy by Gilead could retain (let alone for 15 years) monopoly profits in a dense market is pure fantasy. On this ground alone, the complaint has to be dismissed before trial because the judicial hypothetical has not the remotest chance of being proved against this uncontroverted evidence.

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[33] *See Matsushita Electric Industrial Co*. supra note 12, 475 U.S. at 589-90 (1986):

> The success of any predatory scheme depends on *maintaining* monopoly power for long enough both to recoup the predator's losses and to harvest some additional gain. Absent some assurance that the hoped-for monopoly will materialize, *and* that it can be sustained for a significant period of time, "[t]he predator must make a substantial investment with no assurance that it will pay off." Easterbrook, Predatory Strategies and Counterstrategies, 48 U. Chi. L. Rev. 263, 268 (1981). For this reason, there is a consensus among commentators that predatory pricing schemes are rarely tried, and even more rarely successful. See, *eg.,* Bork, [The Antitrust Paradox, 1978] *supra,* at 149-155; Areeda & Turner, Predatory Pricing and Related Practices Under Section 2 of the Sherman Act, 88 Harv. L. Rev. 697, 699 (1975); . . Koller, The Myth of Predatory Pricing — An Empirical Study, 4 Antitrust Law & Econ. Rev. 105 (1971); McGee, Predatory Price Cutting: The *Standard Oil (N. J.) Case,* 1 J. Law & Econ. 137 (1958).

[34] See, e.g., Matsushita, 475 U.S. 589. The logic here is that the initial lowering of prices increases demand, and thus forces the potential predator to face increasing marginal costs to meet the extra demand, which create large losses. So when the scheme ends, competitors on the sidelines now come back into the market to eliminate the recoupment phase. There are some reservations about the doctrine, see Christopher Leslie, Predatory Pricing and Recoupment, 113 Colum. L. Rev. 1695, 1720-30 (2-13), which point to either the ability to recoup in other markets, which is not remotely possible here or that recoupment is possible through cartel or oligopoly pricing, which are illegal means that could be independently challenged, but for which there is zero evidence here.
. Id,1720-30.

Even if plaintiffs' allegations were somehow sufficient to plead a case under *Twombly*, it should fail on summary judgment. The plaintiffs have offered no evidence whatsoever to exclude all sorts of independent reasons available to explain Gilead's conduct, as is required by the summary judgment standard awarded to defendants in major antitrust cases. There is no reason to use a lower standard of judgment when the antitrust case is cloaked in the so-called product hopping case that also presupposes some (nonexistent) monopoly power. That is the clear message of the bellwether case of *Matsushita Electrical Industrial Co., Ltd. v. Zenith Radio Corp.*,[35] which states:

> If the factual context renders respondents' claims implausible, *i.e.,* claims that make no economic sense, respondents must offer more persuasive evidence to support their claims than would otherwise be necessary. To survive a motion for a summary judgment, a plaintiff seeking damages for a violation of § 1 of the Sherman Act must present evidence "that tends to exclude the possibility" that the alleged conspirators acted independently.[36]

The similar position was expressed in *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*:[37]

> The complaint alleges that Verizon denied interconnection services to rivals in order to limit entry. If that allegation states an antitrust claim at all, it does so under §2 of the Sherman Act, 15 U. S. C. §2, which declares that a firm shall not "monopolize" or "attempt to monopolize." *Ibid.* It is settled law that this offense requires, in addition to the possession of monopoly power in the relevant market, "the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States* v. *Grinnell Corp.*, 384 U. S. 563, 570–571 (1966). The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices—at least for a short period—is what attracts "business acumen" in the first place; it induces risk taking that produces innovation and economic growth. To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*.[38]

These remarks are especially relevant here. As shown before, Gilead did not possess monopoly power for either drug. But even if it had, it engaged in no conduct that could attract the antitrust

[35] 475 U.S. 574(1986).
[36] *Id.* at 586 (internal citations omitted).
[37] 540 U.S. 398 (2003).
[38] *Id.* at 407.

laws. So as the monopoly claim withers, the alleged fraud claim remains the plaintiffs' only lifeline.

D. The Flawed Fraud Claim

The second part of the plaintiffs' claim is that Gilead engaged in a fraud on the market when it stopped development of TAF in 2004 and announced that it was discontinuing its work on GS 734 (what would eventually become TAF). It issued a press release stating 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."[39] It explained 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." That result is flatly inconsistent with the plaintiffs' inventive narrative that the research was halted because the results in question were *so good* that the product had to be kept under wraps, at great financial cost, for about 12 years. The plaintiffs did not offer any evidence refuting Gilead's medical claim that the trials did not support further research at the time, which was widely accepted at face value in the industry. The appellate court did note that in its support of its summary judgment motion, Gilead stated that it "resumed work on TAF in 2011 and conducted a Phase III study to compare TDF- and TAF-based medications in 2013. That study, as Gilead noted, provided "substantial evidence that TAF had less impact than TDF on renal function [and] bone metabolism."[40] But that point picks out, with the benefit of hindsight, a single feature of the drug, and never once asks whether TAF has (as it does) its own side effects and limitations that explain why and when the decision was made. Of course, Gilead had to anticipate some overall improvement to justify further research, but that hardly shows that it or indeed anyone knew at any relevant time that TAF was unambiguously both better and safer than TDF. At the very least, any plaintiff whose side effects occurred before TAF could be brought to market has no claim at all. And for those who got side effects later, there is no reason to think

[39] Press release, Gilead Discontinues Development of GS 9005 and GS 7340; Company Continues Commitment to Research Efforts in HIV, October 21, 2004, available at https://www.gilead.com/news-and-press/press-room/press-releases/2004/10/gilead-discontinues-development-of-gs-9005-and-gs-7340-company-continues-commitment-to-research-efforts-in-hiv.

[40] Gilead case, 317 Cal. Rptr.3d at XXX.

that when both TDF and TAF were on the market, they all would have opted for the latter drug when the former was still on the market and cheaper because of generic competition. In addition, the finding that TAF had less effect on renal function and bone metabolism explains why Gilead continued the research at a rapid pace, but it does not support the claim that the drug was both faster and safer in all dimensions, given that other elements of drug approval had yet to be independently established.

Without evidence, the plaintiffs insist that this announcement was all a ruse to "falsely claim" that "TAF was not different enough from TDF to warrant further development," in a campaign led by Dr. Martin who had led the effort to get Gilead to develop TDF and TAF in the first place.[41] Yet there was no effort to look at the underlying studies to falsify the conclusion, and it beggars the imagination that the entire research program could be silenced to allow this pie-in-the sky monopolization scheme to proceed, given that the standard elements of fraud have not been pleaded. The Restatement (Third) of Torts summarizes the legal standard for fraud as follows:

> One who fraudulently makes a misrepresentation of fact, opinion, intention or law for the purpose of inducing another to act or to refrain from acting, is subject to liability for economic loss caused by the other's justifiable reliance on the misrepresentation.[42]

First, absent an adequate allegation that TAF was better than TDF in all dimensions and Gilead had knowledge of such, there can be no "misrepresentation." Second, even if there had been, fraud requires inducement, and as no affirmative duty exists to market a new drug in the first place, nothing about withholding information about a new drug could plausibly constitute inducement to purchase an existing drug.

There is also good reason why the Federal Rule of Civil Procedure 9(b) carries an exacting standard for pleading fraud that is clearly not satisfied here:

> Fraud or Mistake; Conditions of Mind. In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.

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[41] Complaint, ¶ 79.

[42] RESTATEMENT (THIRD) OF TORTS §9. There is for these purposes no material difference between the Second and Third Restatements: The Second Restatement reads:

> One who fraudulently makes a misrepresentation of fact, opinion, intention or law for the purpose of inducing another to act or to refrain from action in reliance upon it, is subject to liability to the other in deceit for pecuniary loss caused by his justifiable reliance on the misrepresentation.

RESTATEMENT (SECOND) OF TORTS § 525 (1977).

The threadbare allegations fall far below this pleading standard. The 2004 decision to stop work on TAF was made three years after TDF was on the market, and doing well. After this decision was made, there was then a seven-year gap until 2011 when Gilead renewed the research, for which the easy explanation is that the information gained in the interim seven years merited a reevaluation of the earlier results. At that time, it was full speed ahead, for notwithstanding the usual difficulties with clinical trials and the FDA review process, TAF went onto the market in 2016 when the patented TDF still maintained a powerful market position.

It is therefore no surprise that the question of fraud, on which the plaintiffs hang their case, has been investigated in the academic literature, but from the opposite direction. Serious academic protests charged that the vigorous plaintiffs' lawyers, in an effort to obtain clients, engaged in a campaign to spread disinformation to the public at large. The point was put this way in one publication:

> Community groups, researchers, and providers have been raising alarms that ads for lawsuits that perpetuate rare side effects caused by TDF/FTC may be hindering progress to disseminate PrEP in the communities most heavily impacted by HIV. However, to our knowledge, there have been no empirical studies to investigate this. In our geographically diverse sample of participants in an ongoing cohort study, we observed that 59.9% had seen ads for TDF lawsuits on their social media. And, more alarming, 38.2%, said that seeing lawsuit ads made them question the safety of PrEP.[43]

Indeed, one exhaustive review study based on a meta-analysis of literature noted that TDF remains a component of any regime intended to treat HIV, and stresses the need to keep up to date with kidney and bone disease, the known negative side effects.[44] But at no point does this notification even hint that some fundamental change in the legal regime is required to deal with that known risk. Against this background, the plaintiffs' barebones fraud story makes it more likely that people in need of treatment will not get it because of the fearmongering found in this litigation.

E. Inflated Damage Calculations

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[43] Christian Grev et al, Marketing of Tenofovir disoproxil fumarate (TDF) lawsuits and social media misinformation campaigns' impact on PrEP uptake among gender and sexual minority individuals, AIDS Behav 2021 May 25(6): 1396-14-4. available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7854969/.

[44] For discussion, see L. Chan et al., Potential Kidney Toxicity from the Antiviral Drug Tenofovir: New Indications, New Formulations, and a New Prodrug, Current Opinion in Nephrology and Hypertension, https://journals.lww.com/co-nephrolhypertens/abstract/2018/03000/potential_kidney_toxicity_from_the_antiviral_drug.8.aspx (2018), also available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6103211/.

Next, one key element of the supposed grand strategy for the sale of TDF and TAF was that the scheme (of selling a supposedly inferior product!) would prove so profitable that it would allow Gilead to make a handsome profit—to the tune of an additional $5 billion from pausing the sale of TAF products—even if they were found out and then held liable for the 25,000 cases of people—"5,000 killed, 20,000 injured"—harmed by various forms of kidney and bone ailments.

Those numbers do not add up. Start with the simple calculation of the expected liability for actual damages in one such case. It is often difficult to determine whether death or injury cases are more expensive to deal with, but for this initial approximation those subtle variations do not matter.[45] Twenty-five thousand cases at $1 million per case (a modest figure these days) translates into $25 billion in damage awards for a product—a prohibitive figure. But that number is just the start: The expenses of defending these cases—internal personnel and resources, external counsel, expert fees, public relations and brand management, for starters—could easily run up to 50 percent of any damage award. And if the plot were as cold-blooded as alleged, punitive damages equal to or greater than the actual damages would be in order in each of these cases, along with criminal sanctions against the firm and all its key participants. 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.[46]

It is, therefore, sheer fantasy to assume that Gilead could contemplate this self-destructive strategy, as insinuated in the oral argument exchange excerpted above. Rather, we must assume Gilead believed that both TDF and TAF had strong safety profiles, consistent with their long-term marketplace successes as both a proprietary and generic drug. Their total sales were about $65.283 billion for the entire period from 2001 to 2023, which would be swamped by the total tab for a foolhardy venture. The parallel numbers for TAF from 2015 forward were $76.369 billion, which reflects in part the inflation from 2001 to 2015. Accordingly, if Gilead had been silly enough to try this strategy, it would bankrupt the firm that had produced two highly regarded blockbuster drugs. Yet the actual numbers of alleged cases of adverse side effects of TAF, both absolutely and relative to TAF products (a topic to which we shall now turn), clearly confirms that TDF products

[45] The difficulty lies in whether pain and suffering damages are cognizable for death (when it is unclear whether the victim has experienced great pain) as they are for injuries just short of death, where the suffering is apparent. Paradoxically to some, the greater injury of death can result in lesser compensation.

[46] For the market capitalizations, see https://companiesmarketcap.com/gilead-sciences/marketcap/.

have a strong safety profile, consistent with their long-term usage on the marketplace as both a proprietary and generic drug.

F. The Court of Appeals' Erroneous Decision

At this point, it is incorrect to allow the plaintiffs to advance idle talk of fraud and concealment about actions that took place 20 years earlier, for which the defendants gave the most common of reasons for not continuing a given line of research. There are many potential new drugs; any regime that, with the benefit of hindsight, commits a judicial determination of some 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 those products. The Court of Appeals shows no institutional awareness of how drug development works when it writes in response to the charge that these cases are unmanageable:

> On the contrary, their negligence claim is premised on Gilead's *possession* of such an alternative in TAF; they complain of Gilead's knowing and intentional *withholding* of such a treatment following its invention. While we agree with Gilead that a duty that placed manufacturers "under an endless obligation to pursue *ever-better* new products or improvements to existing products" would be unworkable and unwarranted, plaintiffs are not asking us to recognize such a duty.[47]

It is of course the case that no one has ever imposed on any company any duty to devise from scratch some unknown new product to deal with an established condition. Yet in this instance there was no evidence whatsoever that in 2004 Gilead had certain knowledge of the success of a compound on which its most recent tests were negative. No court, no jury, and not even the FDA is in a position to decide, or second- guess, the investment decisions running into the billions of dollars which are needed to bring drugs to market. Indeed, risk is the dominant social reality. The foundational article in this field is by Joseph A. DiMasi, Ronald Hansen and Henry Grabowski, dating from 2003, whose basic procedures are still sound today.[48] The bottom line at the time of their research put the cost of a new chemical entity, NCE (i.e., a breakthrough chemical), at $403 million (equivalent to $729 million today).

That basic number reflects the costs of those drugs abandoned in development, which is a routine occurrence given the battery of basic chemical tests and clinical trials that have to be

[47] 98 Cal. App. 5th 911, 921 (2024).

[48] Joseph A. DiMasi, Ronald Hansen &j Henry Grabowski The price of innovation: new estimates of drug development costs, 22 (Issue 23) J Health available at https://www.sciencedirect.com/science/article/abs/pii/S0167629602001261?via%3Dihub.

conducted. 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 to be about 11 percent per year. That high discount rate is attributed to the riskiness of the venture. That correction then raises the price for a typical drug in 2000 to about $802 million for a chemical entity, or about $1.45 billion today.

The key blunder in the Court of Appeals opinion speaks of "Gilead's knowing and intentional *withholding* of such a treatment following its invention." That most unfortunate phrasing makes it appear as though the "invention" of some new patented entity was ready for sale, as if there were bottles of pills on the shelves ready for delivery. But what Gilead had in 2004 and 2011 was a TAF prodrug compound that had to go through massive transformations, including animal and clinical tests, before it could reach 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.

The Court of Appeals also states that, on the plaintiffs' view, "what matters is that 'Plaintiffs and their physicians were deprived of the *choice* between TDF or TAF by Gilead's actions'"[49]—words that do not appear anywhere in the complaint. But there are two insuperable objections to that account. The first is that to develop TAF, Gilead could easily have been forced to divert resources from promoting TDF, which could have easily delayed its market success, causing serious losses during the period when TDF, the first product in a class, was not generally available. Second, the plaintiffs took the incorrect position that TDF could *not* have found any market niche given the supposed dominance of TAF on both safety and effectiveness. On that supposition, only the one product would have been used at all, which again has proved false given the complementary and widespread simultaneous use of both drugs. Hence, a clearer understanding of the institutional constraints makes it clear that the Court of Appeals' supposed limitation on the duty to develop offers no real protection against the ad hoc imposition of duties to development that no one thought existed at the time.

[49] 98 Cal. App. 5th at 919.

The moment the decision in the *Gilead* case came down, multiple criticisms of the opinion noted the massive amounts of dislocation that would necessarily be created by the imposition of this judicial duty, contributing to added costs and uncertainty that would necessarily retard new drug development.[50] So the systematic question is simple enough. Has the plaintiffs' complaint, as interpreted by the Court of Appeal, been able to identify some subset of easy cases that can be allowed without upsetting the entire process of drug innovation? Implicit in Gilead's categorical negative answer to the initial inquiry was that the answer to the latter question was no. And indeed that remains the correct answer once the full implications of the plaintiffs' theory are laid out. The class of cases that the plaintiffs postulate is empty. All the reasons why this case does not offer some tidy verification of plaintiffs' complaint are present in *every* case of drug development. It is an empty set of cases in which the total dominance of one product's safety and effectiveness over another has been established. That is doubly so early in development, when the path forward includes running future clinical trials, FDA approvals, patent objections, and marketing difficulties. So, when it comes to choosing which new drugs to develop, the winnowing process starts early on. As hard choices have to be made, no one drug dominates in every dimension over another. There are tradeoffs galore not only in their medicinal properties, but also in their stability, cost of storage, manufacture, administration, and a lot more. Thus, neither the patent system, nor the FDA, nor the marketing skills of the various companies are ever perfect.

Indeed, as I wrote some years ago, the entire system is fraught with an unhappy mixture of difficult trade-offs and avoidable blunders at every stage.[51] The real task of reform is to make structural changes on various margins so that the overall productivity of the pharmaceutical system can be improved incrementally. But on that task, the judicial creation of this new duty out of whole cloth is an open invitation to disaster. And, as will become clear, it is only a

[50] See, George Priest, California's Negligence Tort Empowers Juries, Hurts Innovation, Bloomberg News, Fe. 14, 2024, available at https://news.bloomberglaw.com/us-law-week/californias-negligence-tort-empowers-juries-hurts-innovation ("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, Orange County Register, February 16, 2024, available at https://www.ocregister.com/2024/02/16/how-legal-adventurism-stifles-medical-innovation/

[51] See Richard A. Epstein, Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation (Yale 2006).

misapplication of the tort law that deals with the question of duty that could have paved the way for such a disastrous judicial intervention as rendered in this case by the Court of Appeals.

III. WHY PLAINTIFFS FAIL TO MAKE OUT A DUTY OF CARE CASE UNDER CALIFORNIA LAW

The plaintiffs' complaint is not incredible on its facts, but also on matters of law that are so severe that they invalidate their entire case under California law. The Court of Appeals badly erred inventing this new tort duty of "latter stages" of commercialization on defendants, which becomes clear from a historical review of doctrinal developments in the law of torts that the plaintiffs badly misread.[52] It is not credible to think that from its humble origins in *Rowland v. Christian*, decided in 1968, the case law supports the radical transformation of the duty of care in California.

At the highest level of generality, California courts have tended to rely on two key elements to shape the negligence inquiry from which new duties are formed. The first of these is Civil Code Section 1714, which states the statutory rule of negligence :

> Everyone is responsible, not only for the result of his 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.[53]

The second is the following test from *Rowland v. Christian*, which seeks to examine deviations from that general rule:

> 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. Biakanja v. Irving, 320 P.2d 16 (Cal. 1958).[54]

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[52] See Gilead Tenofovir cases, footnote 3:. We use the term "invent" here, rather than "develop," because the meaning of "develop" in the pharmaceutical context is ambiguous. Gilead refers to the entire process of drug creation, from invention through FDA approval, as drug development. Because plaintiffs' claim is focused only on the latter stages of this process, Gilead's general reference to a "duty to develop" obscures the precise nature of plaintiffs' claim he drugs.

[53] Civ. Code, § 1714, subd. (a).

[54] In *Biakanja v. Irving*, which made no reference to Section 1714, even though the opinion in *Rowland* strongly suggest that the rule was in fact distinct to California when it was of common law origin.. Thus in *Biakanja* the plaintiff was entitled to receive all the property under the will of his late brother, but the notary public failed to do the routine

Rowland sought to reconcile the basic rule of negligence, which called for a sliding scale of culpability that it attributed Section 1714 with the dominant common law rule on the liability of property owners and occupiers, which had uniformly applied three distinct categories—invitees, licensees and trespassers. [55] Under that categorical approach the duty an occupier owed to a licensee was to warn of latent defects that were not corrected, which was what happened when Ms. Christian failed to tell her house guest, Mr. Rowland, of a latent defect in the porcelain handle in the bathroom which broke, severing the nerves and tendons in his right hand. *Rowland*'s departure from the common law rule canonized the *Biakanja* factors for the imposition of new duties.

Yet at no point in its erroneous opinion in the *Gilead* ***Tenofovir Cases*** does the Court of Appeals address the enormous gap between *Rowland*'s common social expectation and the unprecedented common law "duty" to develop a potential new drug at great expense and high risk. Indeed, there are some cases in which liability is imposed for the improper use of a defective product under the doctrine commonly known as *negligent entrustment* when a parent gives a nondefective gun to a minor, who then uses it to shoot an innocent bystander.[56] The same would true if that parent were to give an infant an FDA-approved drug that the unsupervised child promptly misuses in ignorance, to the harm of either the child or some third party. In both cases, the closeness in time and space of the connection between the oversight and the ultimate harm is literally in the same visual frame, giving rise to few, if any, troublesome questions of application. Recent appellate cases of negligent entrustment are rare in the published reports precisely because

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paperwork, so that the plaintiff received only one-eighth of his brother's estate. The decision held that it was better for the notary to assume a duty outside contract rather than leave the plaintiff remediless for a financial loss easily preventable by routine steps. It was settled that the heirs could not be compelled to surrender their vested rights. *Biakanja* followed the famous New York case of *Glanzer v. Shepard,* 135 N.E. 275 (NY 1922) which held that 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.

Deleted: *Biakanja* made no reference to Section 1714.s in

[55] "To the invitee, or visitor on business premises, there is a duty to take reasonable care, which includes the duty to seek out those hidden defects that can be discovered by reasonable and routine inspections customary in a particular line of business. To the social guest, there is no independent duty to seek out defects, but there is a duty either to correct latent defects known to the occupier, or to warn the guest of that hidden trespasser. And to the trespasser, there is only the duty to avoid willful and wanton injury. The logic of this position has nothing to do with the foreseeability of injury, for such is possible in all cases with all kinds of defects." *Robert Addie & Sons (Collieries), Ltd. v. Dumbreck*, [1929] A.C. 358 (Scot.). Id. per Dunedin, Viscount.

[56] "[A] person who turns over a firearm to a child who lacks special training and experience is subject to tort liability under the rules relating to negligent entrustment." RTT: PEH §10, cmt. f.; see, e.g., Sullivan v. Creed, [1904] Ir. R. 317 (K.B.) (cocked and loaded gun left on gate). For general discussion, Richard A. Epstein, Torts, §5.5 (1999).

there is no dissatisfaction with the current rule by any judge, academic, practitioner, or institutional player. But the massive gap in time and space should pose a strong barrier against the unprecedented judicial recognition or creation of legal duties in the very different context at bar. The duty to commercialize patentable drugs involves a process with thousands of difficult steps fraught with uncertainty, necessarily taken over decades at the cost of hundreds of millions of dollars. Moreover, the product in question is not put in the hands of an unstable or irresponsible party, as in the negligent entrustment cases cited by the Court of Appeals, but in the care of the FDA, physician specialists, and knowledgeable patients who can be trusted to make, as they have made for several decades, responsible decisions of drug use. Context matters.

Not only did the California Court explore these differences, but at no time did it examine the weakness of the plaintiffs' so-called monopolization and fraud claims, or its wildly erroneous claim, false at the time it was made, that in head-to-head competition TAF would drive TDF off the market.

In light of this sorry mischaracterization of the record, the *Rowland* formulation does not apply at all. There is no "closeness of the connection between the defendant's conduct and the injury suffered" given the many steps to drug approval and successful use. There is "no moral blame attached to the defendant's conduct" whose development of TAF was in accord with sound economic principles (as well as federal regulations). And there was no way that "the policy of preventing future harm" did not point in the opposite direction, for any supposed inquiry into foreseeability has to take into account the exposure to liability will cause companies to steer clear or risky projects lest they be hit with a lawsuit of this dimension. At no point did the court try to explain why either Section 1714 and the *Rowland* test are compatible with the inflated monopoly and flawed deceit claims that lie at the heart of the plaintiffs' case. Moreover, the Court of Appeals offers no explanation as to why the adequate warnings do not help drug users and their physicians make the kind of responsible choices which was not possible for the plaintiff confronted with the latent defect in *Rowland*. Thus, in the *Gilead* cases the Court of Appeals ignored downstream actors' key roles in the ordinary administration of these drugs, even though they shaped the scope of the actions of hospitals and physicians in determining the proper course or treatment in light of known and fully disclosed risks—not latent defects.

A general judicial skepticism concerning the effort to transplant *Rowland* into foreign soil is also evident in the recent California cases that address quite explicitly when one person

should be held liable for the wrongs of another individual, in which the issue of downstream control in a heavily regulated environment comes to the fore. The 2018 California Supreme Court decision, *Brown v. USA Taekwondo,* states the basic legal rule: "Whether a duty exists is a question of law to be resolved by the court."[57] *Brown* then notes the various historical strands that help decide how that question of law should be resolved. The first is: "In California, the 'general rule' is that people owe a duty of care to avoid causing harm to others and that they are thus usually liable for injuries their negligence inflicts."[58] Duty, breach, causation, and damages are said to be the four elements of the tort.

As noted above, the distinctive feature of the *Gilead Tenofovir Cases* is that once the drugs in question were developed, their subsequent use was subject to control under the detailed system of oversight created under the Food and Drug Administration.[59] A parallel issue about regulatory oversight arose in another Section 1714 case, involving financial losses, to avoid creating independent tort duties that clash with established practice. In *Sheen v. Wells Fargo Bank*,[60] a plaintiff, whose loan had been foreclosed, insisted that the bank "owed Plaintiff a duty of care to process, review and respond carefully and completely to the loan modification applications Plaintiff submitted."[61] This court unanimously rejected the plaintiff's claim by noting these questions of duty were all to be resolved as matter of law. *Sheen* concluded that it was unwise for any court to inject an independent tort duty into a relationship that was already fully regulated by a combination of contract and statute. It therefore held that the economic loss doctrine "bars recovery in negligence for pure 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."[62] The plaintiffs in *Sheen* had not cited any statute or regulation that established the processes mortgage servicers must follow in handling modification

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[57] *Brown v. USA Taekwondo,* 11 Cal. 5th 204, 483 P.3d 159 (2021).

[58] *Southern California Gas Leak Cases* (2019) 7 Cal.5th 391, 398.

[59] Indeed the level of direct regulation is so pervasive that, although the issue is not before this court, the plaintiffs' novel theory is preempted by federal law under the seminal case of Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947), observing 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 230.

[60] 12 Cal. 5th 902, 505 P.3d 625 (2022).

[61] *Id.* at 915.

[62] Id.

applications, including the California Homeowner Bill of Rights (HBOR).[63] In words that are fully applicable here, the Court declined to impose a common law duty:

> We are unpersuaded that such a remedy should be created by judicial fiat. 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.[64]

All of these considerations are relevant here given that both state and federal government are active in the regulation of every aspect of drug production dealing with safety effectiveness, warnings, and consumer fraud. It is every bit as impolitic to create an ad hoc duty of massive financial liability that can only disrupt the multiple extant systems of state and federal regulation. Indeed, the basic sensitivity expressed in *Sheen* follows the same cautious attitude toward the judicial creation of duties in physical cases. Thus, any application of an undifferentiated foresight doctrine was sharply limited in *Brown v. USA Taekwondo*,[65] which examined the duty question under an extended *Rowland* framework. Three female plaintiff gymnasts training for the Olympic sport of Taekwondo were repeatedly sexually abused by their coach, who was later banned from the sport and subject to criminal punishment. Structurally, the case calls for a remedy that requires some second-best solution because the truly culpable party does not have the resources to respond to the enormous losses that he inflicted. The imposition of liability on the two other defendants thus depended upon the strong sense that, wholly apart from privity, liability should be imposed only on the party that is in the best position to prevent the loss. In *Brown*, the plaintiffs might well have helped protect themselves, by, for example, reporting the abuses. But its decision was not directed to possible defenses, but instead to the prior question of choosing the proper defendant, be it USA Taekwondo (USAT), the United States Olympic Committee (USOC), or both. Using a two-part test the court "asked, first, whether Brown had adequately alleged a special relationship

[63] Cal. Civ. Code, § 2923.4 et seq.
[64] *Sheen*, 12 Cal. 5th at 945.
[65] *Brown v. USA Taekwando*, 11 Cal. 5th 204, 483 P.3d 159 (2021).

between the parties that gave rise to a legal duty to protect, and second, whether the *Rowland* factors weighed in favor of limiting or eliminating this duty."[66] The Court held that it might well be proper to find that special relationship with USAT which had direct oversight responsibilities for female athletes, but not for the USOC which was one layer further removed from the situation on the ground. Only after that special relationship had been established would the *Rowland* factors come into play. It was the intervention of the second layer of control that protected the USOC, making it clear that any generalized foresight test cannot, without more, distinguish the two cases, because some "foresight" is always given to sentient beings, even those that do not have direct control. And nothing in section 1714, the Court stressed, changed the analysis. To be sure, "Section 1714 states a broad rule, but it has limits. We have explained that the law imposes a general duty of care on a defendant only when it is the defendant who has created a risk of harm to the plaintiff, including when the defendant is responsible for making the plaintiff's position worse."[67] "Where the defendant has neither performed an act that increases the risk of injury to the plaintiff nor sits in a relation to the parties that creates an affirmative duty to protect the plaintiff from harm, however, our cases have uniformly held the defendant owes no legal duty to the plaintiff."[68]

The basic logic of *Brown* received additional support in the recent case of *Kuciemba v. Victory Woodworks*, *Inc*.,[69] 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 for the court to impose a duty of care:

> "The first group involves foreseeability and the related concepts of certainty and the connection between plaintiff and defendant. The second embraces the public policy concerns of moral blame, preventing future harm, burden, and insurance availability. The policy analysis evaluates whether certain kinds of plaintiffs or injuries should be excluded from relief."[70]

It was clear that the distinction between the USOC and the USAT is in accordance with these views. Indeed, given the physical and social distance from the places of actual harm, this

[66] Id. at 211.
[67] Id. at 214.
[68] Id. at 216.
[69] 14 Cal. 5th 993, 531 P.3d 924 (2023)
[70] Id. at 1021-1022.

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.'" quoting *Regents of University of California v. Superior Cou*rt.[71] *Regents* exhibited a very different control relationship. In that case, the defendants were in charge of the university when the plaintiff student was stabbed in a chemistry lab by a fellow student already known to the university officials as suffering 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. Nothing on the policy level undid that conclusion. For it was wholly unlikely that universities would withdraw from affording mental health treatment to its students, given that its extensive obligations under the American with Disabilities Act were reinforced by a powerful set of "market forces," both requiring the university to take overall charge of the situation.[72] 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 involve 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 Court*,[73] the plaintiff's husband carried home his work clothes containing asbestos fibers, which exposed the plaintiff to injury. The question of causation and foresight were settled in the plaintiff's favor because OSHA regulations had identified this precise risk and further specified the correct set of employer protections that could have obviated the plaintiff's harm. Hence, the breach of that independent federal standard generated the legal duty when no new or intervening activity broke 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, it would allow recovery only for members of the employee's household where the "regularity and intensity was highest."[74] The compromise solution found employer

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[71] 4 Cal. 5th 607, 413 P.3d 656 (2018).
[72] Id. at 632.
[73] 1 Cal. 5th 1132, 384 P.3d 283 (2016).
[74] Id. at 1141.

liability in the most salient cases without exposing that firm to an unlimited liability that could sink the company.

That intermediate solution proved unavailing in *Kuciemba v. Victory Woodworks*,[75] where Corby Kuciemba's husband, Robert, was an employee of Victory Woodworks when the City and County of San Francisco issued a health order that placed him in close 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 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,"[76] and that the employer cannot "control whether a given employee will be aware of, or report, disease exposure."[77] 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."[78] And lastly, there was the prospect of crushing liability that could apply even within that limited class of household members. The contrast between *Kuciemba* and the Tenofovir cases could not be clearer. In the former, the defendant was on the scene at the time the violations took place, and even then its partial control was not sufficient for the court to impose a broad legal duty of care upon the defendant.

The dominant theme in these California cases is to put blinders on the foresight principle in order to reduce the imposed duty to a manageable extent. In this regard as in so many others, the California courts follow the same patterns found in common law jurisdictions even when there is some statutory authorization for a broad inquiry, which are then limited in accordance with restrictive common law principles. Thus, a novel effort to expand tort protection was rebuffed by the Supreme Court in *Metropolitan Edison Co. v. People Against Nuclear Energy*.[79] There, the Nuclear Regulatory Commission (NRC) had authorized the restart of one of the idle reactors at Three Mile Island. It then concluded that this decision would not have any significant environmental impact that would block approval. That decision was challenged on the ground

[75] 14 Cal.5th 993 (2023).
[76] Id. at 1026
[77] Id.
[78] Id. at 1027.
[79] 460 U.S. 766 (1983).

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 the Supreme Court held that these psychological harms fell outside NEPA because the notion of foresight was capped by the principles of causation articulated at common law:

> Our understanding of the congressional concerns that led to the enactment of NEPA suggests that the terms "environmental effect" and "environmental impact" in § 102 be read to include a requirement of a reasonably close causal relationship between a change in the physical environment and the effect at issue. This requirement is like the familiar doctrine of proximate cause from tort law.[80]

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."[81] 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,' is to be accomplished." [82]

That proximity condition cannot be satisfied given the vast array of actions that intervene between the initial action and its asserted effect. In similar fashion, The Interstate Commerce Act allows the Commission to approve a rail-line merger if the project "will be in the public interest."[83] Yet, "public interest," like "reasonably foreseeable," does not include every conceivable public benefit. Rather, the public interest was limited by its statutory context to matters that require a ' direct relation to adequacy of transportation service, to its essential conditions of economy and efficiency, and to appropriate provision and best use of transportation facilities.'"[84] The public interest standard did not include judicial weighing of the merits and demerits of the oil and gas industry or the effects on downstream businesses already subject to extensive regulation.

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[80] *Id*. at 774.
[81] *Id*. at 774 n.7.
[82] Id. at 776 (internal citation omitted).
[83] *New York Cent. Securities Corporation v. U.S.,* 287 U.S. 12, 22 (1932) (quoting Interstate Commerce Act, § 5(2))).
[84] *Id*. at 25.

As the U.S. Supreme Court stressed, the term "public interest" may be broad, but it is not so "vague and indefinite" as to allow railroad operators to wander far off in time and space, without any "intelligible principle" to structure its deliberations.[85] In *J.W. Hampton, Jr., & Co. v. U.S.*, the Court addressed a case which in fact involved detailed rules that allowed an administrative agency to make precise tariff adjustments on certain imported goods.[86] The limitations found in these diverse areas deal with the same broad language on which the Gilead plaintiffs hope to pin their entire case. But the institutional setting shows that the normal set of common law restrictions on foresight, such as those in play in California, block this speculative journey into the unknown.

The tangled history of the cases lends no support to the proposition that in this case a product liability claim could be advanced without proof of defect. An examination of the early cases shows that none of them support the creation of a product liability claim under Section 1714. The initial point here is that this section applies a negligence rule when the product liability cases all proceeded under a strict liability theory that made no reference whatsoever to that section. The seminal product liability cases included two early decisions by Justice Traynor in *Escola v. Coca-Cola Bottling Co.*,[87] which dealt with the application of the strict liability rule to an exploding Coca-Cola bottle, and *Greenman v. Yuba Power Products, Inc.*,[88] which dealt with a defective lathe. Yet neither case even mentions Section 1714 in the development of the strict liability rule. That omission is perfectly sensible because the text of that Section only deals with cases of negligence or intentional harm. It contains no reference to that strict liability principle that emerged thereafter under Section 402A of the Restatement Second of Torts, as was the case with other major decisions that elaborated the elements of the new tort.[89] In contrast, as noted, *all* the cases that do fall under Section 1714 involve some *contemporary* activity or oversight by the defendants of the activities engaged in by third parties which are the source of difficulty.

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[85] National Broadcasting Co. v. U.S., 319 U.S. 190, 225 (1943) (rejecting argument that the "standard of 'public interest' governing the exercise of the powers delegated to the Commission by Congress is so vague and indefinite").
[86] 276 U.S. 394, 401(1928).
[87] 24 Cal. 2d 453, 150 P.2d 436 (1944).
[88] 59 Cal. 2d 57, 377 P.2d 897 (1963).
[89] 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*, 20 Cal.3d 413, 573 P. 2d 443 (1978); *Cronin v. J.B.E. Olson Corp*, 8 Cal.3d 121 501 P.2d 1153 (Cal. 1972); *Pike v. Frank G. Hough, Co.*, 2 Cal. 3d 465 (1970).

It is just as instructive that the subsequent development of the tort law was in no way shaped by the earlier cases under Section 1714. Thus, in *Li v. Yellow Cab*,[90] the court "judicially declared" that the common law that treated contributory negligence as an absolute bar to liability was to be jettisoned in favor of a rule of comparative negligence that "assesses liability in direct proportion to fault."[91] It then held that Section 1714 did not "codify" contributory negligence so as to block the change:[92]

> It was not the intention of the Legislature in enacting section 1714 of the Civil Code, as well as other sections of that code declarative of the common law, to insulate the matters therein expressed from further judicial development; rather 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.[93]

The court reinforced that point elsewhere:

> The statement in some cases to the effect that section 1714 states a civil law rather than a common law principle (see *Rowland* . . .) is correct insofar as it indicates that the duty to refrain from injuring others through negligence has its roots in civil law concepts. It is incorrect, however, insofar as it might be read to indicate that defenses affecting recovery for breach of that basic duty are also rooted in the civil law. As we have shown, the defense of contributory negligence and its mitigative corollary, the doctrine of last clear chance, as they are stated in the statute, are clearly of common law origin.[94]

Li thus was in line with the evolution of the law that took place throughout the common law world. These cases 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.[95] *Rowland* has not prevented California's active judicial development of the twin concepts of proximate causation and duty of care, as is evident in all the cases examined above.

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[90] 532 P. 2d 1226 (1975).
[91] Id. at 1229.
[92] Id. at 1229.
[93] Id at 1233.
[94] Id. at 1237, n. 15.
[95] See Schwartz & Rowe, *Comparative Negligence*, Appendix A (5th ed. 2018).

Nor do any of the other precedents mentioned by the plaintiffs carry any weight. In *Mexacali Rose v. Superior Court*,[96] the plaintiff was served a chicken enchilada by the defendant restaurant owner that contained a one-inch chicken bone that caused serious throat injury when swallowed. The earlier precedents only allowed recovery for foreign material contained in the enchilada,[97] but not for natural substances. *Mexacali Rose* held that the "reasonable expectations" of the plaintiffs were for an enchilada free of both bones and foreign materials. *Rowland* and Section 1714 were cited, but for a result that was not only reasonably foreseeable, but virtually certain given the tight physical frame of the incident. The Court of Appeals cited this case for the proposition that a defendant could be liable for a defect that it did not create—the chicken bone—without explaining how that decision supported the creation of a duty in the *Tenofovir Cases* with their infinitely longer and more complex causal chains.[98] The Court of Appeals insisted that the defendants "provided no justification for restricting the decision to food products" further noting that "[i]mportantly, Mexicali Rose illustrates the continued utility of the negligence cause of action in products liability actions."[99] Both of these points are true but neither of them comes close to justifying the new duties in the Gilead *Tenofovir Cases* that span decades and miles.

Recall that plaintiffs' assertion is not a negligence claim against TDF on its own, which would be required to even begin an analogy to any food products cases. Rather the claim is that the risks of TDF should have mandated the defendants to put TAF onto the market, and that the failure to do so was culpable. That, however, is an affirmative duty couched as an ordinary duty. As described above by *Brown*, affirmative duty claims require either a special relationship or prior creation of the risk. No special relationship claim is colorable, and therefore the most charitable argument that can be made within the doctrine on behalf of the plaintiffs is on the ground of prior creation of the risk. Yet the "prior creation of the risk" theory of affirmative duty in tort does not consider risk in isolation. Instead, it considers risk and reward in combination. In the prototypical prior creation of the risk case, in which a driver's vehicle stops on the car through no fault of her own, yet the driver is liable for failing to set up a warning flare, the conduct which creates the risk is one which is all cost and no benefit to the injured party. For an affirmative duty to lie, the prior,

[96] 1 Cal. 4th 617, 822 P.2d 1292 (1992).
[97] Mix v. Ingersoll Candy Company, 6 Cal. 2d 675, 59 P.2d 144 (1936).
[98] 98 Cal App 5 at 926.
[99] Id.

non-negligently created risk must be without offsetting concomitant benefits. Here, the plaintiffs' affirmatively purchased TDF being fully apprised of the risks, and must be presumed to have done so because the benefits outweighed the costs. To extend an affirmative duty anytime one drug has risks in the form of side effects threatens to undermine the whole law of products liability and affirmative duties in one fell swoop.

The Court of Appeals also examined *Merrill v. Navegar*,[100] which refused to hold a gun manufacturer responsible for the mass killings and woundings committed by a third party using semiautomatic assault weapons, given the statutory exemption for liability for the use of legal nondefective guns. It is hard to connect this sensible result to the denial of liability of the defendants on either negligence or strict liability. But the Court of Appeals ignored the obvious factual differences by insisting that *Merrill* requires proof of defect in product cases even though that holding has never been applied to negligent entrustment cases. Yet the Court of Appeals does not explain why *Merrill's* fact pattern remotely resembles the *Tenofovir Cases* where the completed products were handed down a chain of production.[101]

What is striking about the Court of Appeals' opinion is that at every point it flees to such high levels of abstraction that it is not possible to discern the facts of the quoted cases, and it is not possible to even know when its expanded vision of tort duty was in fact already rejected in those same cases. Thus, the Court of Appeals in the Tenofovir cases frequently referenced the decisions in *Taekwondo* and *Kuciemba*, but only for vacuous general propositions that never gave the slightest indication that the former case denied liability for the USOC and the latter case did the same for the defendant employer. And the reason for that evasion was clear. By staying at the highest level of abstraction, that court never had to grapple, even once, with multiple levels of supervision. Nor did it even attempt to show that the defendant here had the same kind of effective control that was found in *Brown* or that the powerful presence of an extensive regulatory regime precludes the imposition of a common law duty of care as in *Sheen.*

Hence the two distinct factors unambiguously call for the rejection of this duty. Starting with foresight, a generalized duty is impossible to sustain, given the limitations of the foresight test insofar as it downplays all the actions of other individuals or institutions whose actions followed any decision about drug development. Rather than face that inquiry at a general level,

[100] 26 Cal. 4th 465, 28 P.3d 116 (2001).
[101] 317 Cal. Rptr. 3 at 151.

the Court of Appeals held that the foresight is found solely because of the evident false trope that the new drug was at least as effective and safe as the earlier one. But the exhaustive review of the evidence shatters that claim. For example, the Court of Appeals writes "the fact of injury is certain," but only after the fact when the claim was brought. In fact, before the claim, the percentages of cases that arguably involved any injury was tiny and, in any event, subject to adequate warnings. Given those low rates and how often the injuries occur, why assume that people would turn down TDF given a minor risk when the drug was used as directed millions of times over the year, with the blessing of every major medical establishment? The issues of causation here are far more intricate than in *Rowland* because FDA approval, physician advice, and patient choice play out different ways in each of thousands of individual cases. Indeed, as the Court of Appeals noted, obtaining FDA approval was typically a one-in-eight chance,[102] so how could the approval of TAF have been a certainty in either 2004 or 2011? The evidence that TAF has desirable features shows that it should have been developed and marketed. It does not show that TAF had, or could have had, absolute dominance over TDF, especially since the public record confirms that both drugs are regarded as highly useful and effective. The claim that Gilead greedily eyed some future monopoly in anti-viral ignores the wide range of competitive products in the market for TAF; that the FTC Orange book rules make it impossible for anyone to take so valuable a drug off the market; and that Gilead priced it low to gain market share. It is also worth remembering that the medical profession spoke out strongly against the supposed dangers of TDF as fearmongering. All of this evidence and more set out in the first section of this paper has been stonewalled by the plaintiffs and the Court of Appeals. This case is ripe for a motion to dismiss, for summary judgment, or both. This case does not come within miles of the negligent entrustment cases where guardians must keep these products from the hands of infants and incompetents. Rather, the public record fully supports the view that both TDF and TAF are safe and effective products, and that the world would be a worse place if the legal system pounced on the sale of TDF as if it were a social cost and not a social blessing, as it has always been.

IV. CONCLUSION

[102] 98 Cal. App. 5th at 939.

This case is borne of a collection of regrettable allegations that show how easy it is for civil litigation to go off the rails. The *Tenofovir Cases* seek to elicit sympathy with the plaintiffs' outlandish hypothetical: that Gilead hatched an evil plot to suppress one drug for years in order to preserve a monopoly for TDF, which hit the market before its complementary anti-viral TAF. But there is no evidence that any covert monopolization by product hopping, or indeed any other illicit practice, did or could have taken place. All the evidence points to Gilead's rational initial decision in 2004 not to develop a drug that had twice appeared to have no beneficial anti-viral effects. At this point, the misreading of all the duty precedents, without looking at the abundant public evidence, leads the plaintiffs to advocate massive distortions on California's judicial requirements for the creation of legal duties. If this standard survives this case, then it will be applied in future cases in ways that are certain to send the arduous process of new drug development into a tailspin from which it could never recover. The plaintiffs' case is wrong on the facts and the law. Its arguments, and the decision of the Court of Appeals below, should be promptly repudiated by the California Supreme Court.