A165558

IN THE COURT OF APPEAL
OF THE STATE OF CALIFORNIA
FIRST APPELLATE DISTRICT, DIVISION 4

GILEAD SCIENCES, INC.,
Petitioner,

v.

SUPERIOR COURT OF THE STATE OF CALIFORNIA,
COUNTY OF SAN FRANCISCO,
Respondent,

GILEAD TENOFOVIR CASES,
Real Parties in Interest.

CASE NO. CJC-19-005043
HON. ANDREW Y.S. CHENG, TRIAL JUDGE
SAN FRANCISCO COUNTY SUPERIOR COURT

REAL PARTIES IN INTERESTS' RETURN TO PETITION FOR PEREMPTORY WRIT OF MANDATE, PROHIBITION, OR OTHER APPROPRIATE RELIEF

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APPELLANT/ PETITIONER: GILEAD SCIENCES, INC. RESPONDENT/ REAL PARTY IN INTEREST: SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN FRANCISCO	

CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

(Check one): [x] INITIAL CERTIFICATE [ ] SUPPLEMENTAL CERTIFICATE

Notice: Please read rules 8.208 and 8.488 before completing this form. You may use this form for the initial certificate in an appeal when you file your brief or a prebriefing motion, application, or opposition to such a motion or application in the Court of Appeal, and when you file a petition for an extraordinary writ. You may also use this form as a supplemental certificate when you learn of changed or additional information that must be disclosed.

1. This form is being submitted on behalf of the following party *(name*): Plaintiffs and Real Parties in Interest A.C., et al.
(Full list of Real Parties in Interest submitted by Petitioner on July 6, 2022)

2. a. [x] There are no interested entities or persons that must be listed in this certificate under rule 8.208.

   b. [ ] Interested entities or persons required to be listed under rule 8.208 are as follows:

	Full name of interested entity or person	Nature of interest *(Explain):*
(1)		
(2)		
(3)		
(4)		
(5)		

[ ] Continued on attachment 2.

The undersigned certifies that the above-listed persons or entities (corporations, partnerships, firms, or any other association, but not including government entities or their agencies) have either (1) an ownership interest of 10 percent or more in the party if it is an entity; or (2) a financial or other interest in the outcome of the proceeding that the justices should consider in determining whether to disqualify themselves, as defined in rule 8.208(e)(2).

Date: September 19, 2022

Holly N. Boyer
(TYPE OR PRINT NAME)

s/ Holly N. Boyer
(SIGNATURE OF APPELLANT OR ATTORNEY)

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INTRODUCTION

"Never before has a court – in this State or anywhere else – held that a plaintiff can recover damages for injuries allegedly caused by a non-defective product. That is, until now."

This statement is the core of Gilead's entire Petition. And it is unequivocally false, especially in California where our Supreme Court has long since observed that a "finding of no product defect is not necessarily inconsistent with a finding of negligence" nor does it preclude all other liability on the part of the defendant. (*Hernandez v. Badger Construction Equipment Co.* (1994) 28 Cal.App.4th 1791, 1829, citing *Hasson v. Ford Motor Co.* (1977) 19 Cal.3d 530, 541, overruled on other grounds in *Soule v. General Motors* (1994) 8 Cal.4th 548, 574.) The appalling conduct at issue in this JCCP is a stark reminder why this fundamental principle of negligence law has endured in California, and why this Court should once again reject the most recent attempt by product manufacturers like Gilead to artificially narrow their responsibility for the consequences of their actions.

In truth, "appalling" fails to adequately describe Gilead's conduct. While the Petition distorts the allegations and deflects attention from the evidence to distract the Court from the issues, it all but ignores the real gravamen of these cases – Gilead, in a deliberate and documented effort to increase its profits and manipulate its market exclusivity, for years unreasonably withheld its safer TAF formulations of the tenofovir products it knew were causing thousands upon thousands of debilitating and catastrophic injuries to its patients, including Plaintiffs in this JCCP. That the design of the tenofovir products may not be legally "defective" has nothing to do with these claims; instead, Gilead's negligence stems from its calculated and unreasonable actions independent of the design of TDF - actions it knew would cause harm to countless patients, but did any way. The facts demonstrating the magnitude of this deplorable conduct may be

novel or unprecedented, but California law is not and undeniably imposes liability in negligence on Gilead.

Plaintiffs' theory of negligence was unambiguously stated at the outset in their Master Complaint:

> 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 form of tenofovir called tenofovir disoproxil 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 in safety between TDF and TAF, Gilead withheld development of its safer product, TAF, to artificially and unreasonably maximize profits on its TDF-based medications first. As a result, hundreds of thousands of HIV-infected patients, as well as patients taking the drug prophylactically, were exposed to a more toxic form of the drug for more than a decade. These patients, including Plaintiffs, unwittingly and needlessly suffered permanent, debilitating, and sometimes fatal kidney and bone damage.

(1App.45.) The Complaint goes on to specify – in 22 pages of detail – exactly when and how Gilead chose to put profits over patient safety. (1App.46-78.)

After the close of discovery, Gilead moved for summary judgment. But *Gilead's motion presented no evidence disputing the allegations of the Complaint*. Nor did its Memorandum of Points and Authorities dispute them. Gilead argued simply that no reported case had upheld a claim for negligence on similar facts. Because Gilead, as the moving party, failed to present evidence showing that there was no triable issue of fact regarding the Complaint's allegations, Plaintiffs had no obligation to present evidence

confirming their allegations. Nevertheless, Plaintiffs did so, offering evidence of the facts set forth more specifically below.

Gilead's reply brief below did not dispute any of this evidence. It could not – because *all of this evidence came from Gilead's own documents and deposition testimony.* Instead, Gilead only invoked its consistent theme: there is no reported case allowing a negligence case to proceed to trial on these specific allegations, where there was no claim that the drug used by plaintiffs was defective at the time it was sold. According to Gilead, the duty owed by product manufacturers is *limited* only to theories alleging that the product is itself defective. But that is simply not true.

"California law establishes the general duty of each person to exercise, in his or her activities, reasonable care for the safety of others. (Civ. Code, § 1714, subd. (a).)" (*Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 770.) Section 1714, subdivision (a) provides in relevant part: "Everyone is responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person." (*Id.*) As recently highlighted by the California Supreme Court, "section 1714, 'which has been unchanged in our law since 1872, ***states a civil law and not a common law principal***.'" (*Hoffmann v. Young* (Aug. 29, 2022, No. S266003) __ Cal.5th __ [2022 WL 3711715], citing *Rowland v. Christian* (1968) 69 Cal.2d 108, 112 (emphasis added).)

Thus, and as explained by the Supreme Court on multiple occasions, where a duty exists under Section 1714 or some other source such as negligent undertaking or a special relationship, "we ***presume*** *the defendant owed the plaintiff a duty of care* and then ask whether the circumstances '*justify a departure*' from that usual presumption." (*S. California Gas Leak Cases* (2019) 7 Cal.5th 391, 398 (emphasis added); see also *Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 213-216 [first step is to identify the

source of any duty owed and second step is, if a duty exists, to determine a categorical exception should be carved out for public policy reasons as outlined in a *Rowland* analysis].) It is only where a statutory exception applies or a court recognizes an exception based on relevant policy considerations that a duty is excused. (*Cabral,* at pp. 112-113.)

Gilead has elected to ignore this well-established framework. Instead, Gilead engages in a pompous display of rhetoric – arguing without basis that Plaintiffs seek to impose a "newly-minted duty" on manufacturers to act reasonably in their business decisions – a duty that is "unprecedented" and "radical" according to Gilead. (Pet. at 9,11,28,29,33,47,48,56,62.) Gilead's representation that a categorical exemption exists shielding drug manufacturers from all negligence liability, except to the extent that its negligence results in a defective product, is untrue. As detailed below, there is nothing new in applying the general duty of ordinary care to drug manufacturers. Gilead's attempt to immunize itself from liability for negligence *is* what is unprecedented and unsupported by California law.

Product manufacturers simply do not enjoy the luxury of complete immunity from the duty of ordinary care as suggested by Gilead. Neither the Legislature nor any California court has carved out a categorical exemption for drug manufacturers, let alone product manufacturers generally. While Gilead does not even argue that a categorical exception to the general rule of Section 1714 should be created as to drug manufacturers under a *Rowland* analysis, the policy considerations prescribed by *Rowland* in no way justify a categorical no-duty rule for ordinary negligence claims against drug manufacturers.

Nothing in California's statutes, precedent or policies support limiting negligence liability against those who knowingly expose a vulnerable population to grievous harm solely for profit. A jury must decide

whether Gilead's conduct here was unreasonable and caused thousands of individuals needless pain and suffering. That is precisely the conclusion reached by the Superior Court overseeing this JCCP in denying Gilead's motion for summary judgment and/or adjudication.

For these reasons, and the reasons set out more specifically below, the Superior Court's order should be affirmed and Gilead's Petition denied.

VERIFIED RETURN TO PETITION

In answer to the petition for writ of mandate, Real Parties and Plaintiffs admit, deny and allege as follows:

REAL PARTIES' ADDITIONAL FACTUAL ALLEGATIONS

Gilead's Acquisition and Early Knowledge of Tenofovir's Toxicity

1. In or about 1991, Gilead obtained an exclusive license to synthesize, research, develop and market tenofovir-based antiretroviral compounds for, among other things, the treatment of Human Immunodeficiency Virus-1 ("HIV") in the United States. (3App.1078). At the time it first acquired these exclusive rights, Gilead knew that tenofovir was both poorly absorbed when taken orally and severely toxic to human kidneys when administered intravenously. (3App.1079-1167;8App.2558-2562.)

2. Gilead's initial development of tenofovir thus focused on formulating prodrug delivery mechanisms – combinations of tenofovir with inert salts – that delivered as much tenofovir as possible into target cells without prematurely breaking down in the bloodstream, where it would be filtered through the kidneys and cause catastrophic side effects. (3App.1168-1169.)

3. Gilead's initial prodrug of tenofovir was called TDF (tenofovir disoproxil fumarate). But Gilead knew that TDF still suffered

from disproportionately low absorption in the target cells, and broke down quickly in the bloodstream, and thus it needed 300 milligrams of tenofovir to be effective, leading to high concentrations of tenofovir going directly to the kidneys. (3App.1079-1167;8App.2558-2562.)

The Development of TAF as a Safer Formulation of Tenofovir

4. Years before Gilead ever submitted a New Drug Application (NDA) to FDA for any TDF medicine, Gilead's knowledge about TDF's bone and kidney toxicities led it to initiate a backup program to evaluate dozens of other prodrug combinations of tenofovir with the specific goal of maximizing intracellular concentration of tenofovir while minimizing its systemic concentration thereby reducing the amount of tenofovir to which the body would be exposed and lowering the risk of bone and kidney side effects. (5App.1662-1711.)

5. The result of Gilead's backup program was TAF (tenofovir alafenamide)[1], which was first synthesized in 1998. TAF "was conceived as a low dose version of [TDF] that would minimize systemic exposure to tenofovir, thereby sparing the kidney of any potential [toxicity], and increase the intracellular loading of tenofovir." (5App.1712-1715.)

6. By the early 2000s, Gilead's studies revealed TAF's superior biochemical stability could achieve the same antiviral effect as TDF with only one-tenth (0.1) the amount of tenofovir. (5App.1662-1670,1716-1724). The difference in minimum dosing between TDF and TAF meant that the TAF reduced the amount of toxic tenofovir being filtered by the kidneys by roughly ninety percent (90%), which in turn decreased the risks of renal, bone and tooth injuries in humans. *Id*. By Gilead's own 1999

[1] The Court will note that TAF is referred to as "GS-7340" in Gilead's early development documents. The parties do not dispute that where "GS-7340" is used in a document, the reference is to TAF.

admission, the TAF program was "a spectacular success." (5App.1712-1715.)

7. By September 27, 2002, Gilead had completed a head-to-head comparison of TAF and TDF in human beings (Study GS-120-1101), which showed that 50 mg. of TAF delivered higher tenofovir concentration in HIV infected cells than 300 mg. of TDF. (6App.1851-1877.)

8. With TAF having "*clearly demonstrated proof of concept*" (6App.1907 (emphasis added)), Gilead laid out a detailed schedule for getting TAF to market in 2006. It concluded that a New Drug Application ("NDA") for a TAF-containing HIV medicine could be submitted by June 8, 2006, with expected FDA approval on October 6, 2006. (6App.1970-1982.)

Gilead's Decision to Deliberately Delay TAF Development to Extend its Market Exclusivity

9. Gilead's excitement about TAF was quickly tempered by its realization that sales of TAF would necessarily take sales from TDF as doctors and patients would choose to switch to the superior formulation. (*Id*.)

10. Gilead's officers thus began to express growing concerns internally that TAF would "***cannibalize***"[2] its TDF-based drug, Viread, if not positioned strategically. *Id*. In its April 1, 2003 "Business Review of Key Development Assumptions," Gilead observed that TAF development would result in a significant blow to Gilead's revenue and profits because the "[n]et value of [TAF] needs to be calculating by subtracting [TDF] sales that would be lost to [TAF] (estimated between 70 to 80% of Viread sales

[2]"Cannibalization" "refers to when an existing drug is replaced by a newer generation drug. And most often, that drug will have favorable properties, significantly different properties, and the sales will be taken away from the current to the newly introduced drug." (6App.1939-1948.)

at peak cannibalization)." (Id.) At the time, TDF sales represented a significant portion of Gilead's revenue relative to all other Gilead products, with $566.5 million total sales in 2003 alone compared to $270 million across all other products. (6App.1983-2006.)

11. Gilead was also concerned about the overall impact of generic competition on the profitability of its entire HIV franchise once the patents on its TDF drugs expired in 2017. (6App.2083-2050;7App.2201-2209.) Gilead's former Chief Financial Officer testified that once a name brand drug "goes generic" revenue typically declines 90% and the manufacturer can lose more than 90% of their market share. (7App.2201-2209.)

12. The financial implications of cannibalization and generic competition were so significant that just days after the Business Review meeting, on April 4, 2003, senior management directed the Company's commercial analysts to investigate an alternative strategy for TAF wherein its release would be purposefully delayed in order to coincide with the expiration of TDF's patent in 2017. That e-mail, sent on behalf of Gilead's Executive Vice President of Research and Development Dr. Norbert Bischofberger, instructed Associate Director of Corporate Development Peter Virsik to explore delaying TAF as a franchise extension strategy for TDF:

> As a separate exercise (this is outside the scope of Business Review), Norbert asked us to explore [TAF] potential as an IP extension strategy for [TDF]. Could you Peter work on a quick and dirty model for [TAF] where we extend the patent life from 2017 to 2020? We would take the existing development costs (in the latest assumptions documents) and move them forward, such that we could get [TAF] on the market two years prior to 2017.We also have to determine whether there is any IP around the fixed dose combo, which may extend the patent life even longer? Let's discuss offline.

(6App.2083-2085.)

13. Mr. Virsik completed his "quick and dirty" model on April 14, 2003, which showed that stopping further TAF development only to restart it later in time, so it could be released in 2015 in order to provide Gilead with enough time to convince doctors to switch patients from TDF drugs to TAF drugs before TDF's patent expired in 2017 would result in significantly increased profits to the Company as a result of the manipulation of Gilead's HIV franchise's market exclusivity. Gilead estimated that this loss of HIV market share would continue by fifty percent (50%) year-over-year until it lost roughly ninety-five percent (95%) of the total HIV market to generics. (7App.2201-2209.) However, by intentionally delaying TAF development and submission for FDA approval, Gilead could position TAF to enter the market as a safer, better version of tenofovir than TDF with potentially even longer market protections through at least 2021. In essence, Gilead's scheme to deliberately delay TAF's entry into the market would operate as an artificial extension of the Company's market exclusivity over the sale of tenofovir HIV medications in the United States, leading to increased sales and greater profits than if TAF were released in 2006 as originally scheduled.

14. ***Just three days*** after Mr. Virsik's 'quick and dirty' analysis, on April 17, 2003, Gilead's Development Committee formally adopted this strategy and decided "to stop [TAF] development due to the likelihood that [TAF] would ultimately cannibalize Viread ***regardless*** *of its efficacy and* ***safety*** *profile*." (7App.2151-2154 (emphasis added).)

15. On September 18, 2003, Mr. Virsik sent his final memorandum titled "Financial Analysis of [TAF] as a Tenofovir Exclusivity Extension", effectively formalizing his initial projections from April 2003. (7App.2201-2209.) This analysis confirmed that if Gilead delayed further development of TAF such that it would be re-started in about 2010 and launched in 2015 – two (2) years prior to the expiration of

TDF's patent protections in 2017 – the Company would have time to convince doctors to switch patients from TDF to a TAF-based medicine before generic competitors could encroach on its sales, leading to billions of dollars in additional profits. *Id*. To carry out this scheme, Gilead determined that the TAF clinical studies that were scheduled to begin in 2003 to support approval as originally scheduled would instead be delayed until 2010, thereby delaying submission of TAF for FDA approval. According to the analysis, if Gilead did not adopt this strategy and instead released TAF in 2006 as originally planned, TAF would substantially cut short the life cycle for Gilead's TDF drugs and cause sales to substantially decline as physicians inevitably switched their patients to TAF as the better, safer option. (7App.2223-2263;6App.1983-1988.)

Gilead's Suppression of Material TAF Information to Insulate its Sales of TDF

16. Although Gilead's decision makers favored profits over patient safety, the Company's research scientists and medical advisors believed there was a "high unmet medical need" for TAF" and "support[ed] aggressive development of TAF" based on the favorable nonclinical and clinical data. (7App.2238-22-49; 2264-2273.) Faced with this tension, Gilead's Development Committee took steps to suppress TAF data from the larger medical community, including the doctors and patients who would have opted for TAF instead of TDF if it had been made available to them as originally scheduled. In so doing, Gilead took care to not only put down enthusiasm for TAF, but also to conceal any comparative data that could be interpreted as casting doubt on the safety and efficacy of TDF, which the Company was then touting as the standard of care in HIV therapy.

17. In May 2003, just weeks after the Virsik analysis, Gilead executives met to discuss "how Gilead should manage external communication of [TAF] data and plans" and "ensure dissemination of the

correct commercial messages." (7App.2156-2157.) Though Gilead's decision to stop TAF development was due to its fear that TAF would cannibalize Viread, Gilead did not intend to reveal that fact to investigators or the general public. Instead, Gilead would communicate that "[TAF] would have continued if Viread did not have such an excellent profile" even though it comparatively did not. (*Id*.)

18. Very shortly thereafter, in July 2003, Gilead informed investigators of the GS-120-1101 clinical study that it would not present nor publish the findings, so as "to avoid generating frustration" in the medical and scientific community. (7App.2195.) Not only did this study reveal how much safer TAF is compared to TDF, it also contained data showing that TDF underperformed in terms of anti-HIV activity. (7App.2157.) Gilead's Chief Financial Officer, John Milligan, later admitted that Gilead was concerned about unveiling this study and releasing TAF in the early 2000s because the Company was "trying to launch Truvada (a TDF- containing combination drug) versus [GlaxoSmithKline's combination drug] at that time." "[T]o have our own study [GS-12-1101] suggesting that Viread [TDF] wasn't the safest thing on the market…It didn't seem like the best. It seemed like we would have a mix[ed] message." (7App.2392-2393.)

The Re-Start — Implementation of the 2003 Deliberate Delay Strategy

19. According to Dr. Bischofberger in a memorandum sent to Gilead's Board of Directors, Gilead found itself "at a critical juncture" in the summer of 2010. (8App.2627.) While "Gilead's success to date [was] in large part due to its [sic] contributions to the field of HIV/AIDS," the three TDF-based products that made up ". . . more than 80% of the [Company's] revenues . . ." faced the impending threat of generic competition starting in or about 2018 when patent protections would begin

to expire. *Id*. Gilead's future therefore depended on implementing programs that would ". . . sustain[] revenues through 2018 extending beyond 2025" by ". . . developing new agents that would improve upon [TDF] . . ." *Id*. This "new agent" was TAF, which Dr. Bischofberger described to the Board of Directors in the same summer of 2010 memo as "an improved prodrug of tenofovir that could replace [TDF] with more selective exposure in infected cells resulting in at least equivalent efficacy and ***no side effects on renal function or bone mineral density (approval in 2015)***." (8App.2628 (emphasis added).)

20. Except, TAF was not "new" to the Company at all, nor was the plan to restart its development in 2010 for approval in 2015 a recent decision. Rather, it was the precision execution of a plan to deliberately delay the development and release of TAF that had been meticulously researched, planned and adopted all the way back in 2003 ". . . ***regardless of its efficacy and safety*** . . ." (8App.2627-2628; 7App.2151-2154,2201-2209 (emphasis added).)

21. Beginning in the summer of 2010, Gilead sought to "'re-activate' the existing [TAF] IND", so that it could conduct the remaining clinical trials it had deliberately paused and submit a New Drug Application (NDA) in 2014 for FDA approval by 2015. (8App.2579.) Just as it laid out in 2003, the Company recognized it was imperative that TAF and TAF-based co-formulations be approved by 2015, so that Gilead had time to "convinc[e] HIV prescribers to switch as many patients as possible from a TDF-containing regimen to a [TAF]-containing regimen" before 2017 when generics would begin their efforts to enter the market and siphon sales away from TDF. (8App.2565.)

22. Indeed, just as the Company had outlined in 2003, Gilead's "re-start" aimed to position TAF as a "better option to TDF based on an improved renal and bone safety profile" even though TDF's renal and bone

toxicity risks – as well as TAF's ability to eliminate those risks – were well known to Gilead before it decided to deliberately delay development in 2003. (8App.2567.) Knowing that TAF was a safer and superior prodrug to TDF, in 2010 Gilead began to lay out how it would market TAF to physicians as a better version of TDF. Gilead began the framing of TAF before it even began a single new clinical study of TAF versus TDF and was able to do so based on all of the pre-2003 data it had amassed related to TAF. ***Chief among this data was the GS-120-1101 study that Gilead had suppressed for years in order to conceal the superiority of TAF and underperformance of TDF.***

23. What is more, when Gilead reactivated the TAF IND in September 2010, it disavowed any safety reasons for its prior decision to halt TAF development in the early 2000s, and actually relied on the very same data it generated between 1999-2003 to support FDA approval for its resumed development activities. (5App.1691-1701;8App.2563-2583.) In fact, this same data allowed Gilead executives to continuously tout TAF's superior safety profile to investors in anticipation of launching the drug in 2015, including a 2011 investor presentation — made before any additional clinical data related to TAF existed — where Gilead's Chief Financial Officer Dr. John Milligan described the 2003 plan to deliberately delay TAF development until closer to the patent expiration of TDF a "business decision" intended to maximize sales of TDF:

> Yes, [TAF] is a particularly interesting product. ***It's something that we had discovered many years ago but determined for many reasons including business reasons that it wasn't the right time to take it into the clinic.***

(7App.2392-2393 (emphasis added).)

24. Devastating as it was to its patients' health and safety, Gilead's scheme to deliberately delay TAF's availability was far more

successful than even the Company could have hoped. By deliberately delaying TAF despite knowing it would avoid the injuries caused to thousands by taking TDF, including the Plaintiffs in this JCCP, Gilead was able to protect and extend its tenofovir portfolio, including generating approximately $27 billion in additional profit from tenofovir-containing drugs sold after 2017. (6App.2003.)

RESPONSE TO ALLEGATIONS IN GILEAD'S PETITION

1. Deny the allegations in paragraph 1. (And see Additional Allegations ("AA") #1, *supra*.)

2. Admit. (See AA##6-7.)

3. Admit.

4. Admit. (See AA#4.)

5. Deny.

6. Admit in part, deny in part. Since the time TAF was released to market, it caused thousands of reported and unreported kidney and bone injuries that could have been avoided by TAF. (See AA##2-5.) TAF supplanted TDF as the primary, first-line therapy for the treatment of HIV upon its release, and certain TDF medications were actually removed from the "recommended" category by HHS due to their side effects. (3App.990-995.)

7. Admit in part, deny in part. Deny as to the mischaracterization of TDF saving "many" of the 24,000 lives. Many patients took various regimens of HIV medications, and TDF was actually discontinued in their therapies because of their kidney and bone injuries, thus they are alive today because of other HIV therapies, including TAF.

8. Deny.

9. Admit.

10. Deny.

11. Deny. While Plaintiffs do allege that Gilead concealed material information about TAF, that concealment stretches back to at least 2003. (See AA##11-13,15,17-19.) Further, TAF is not an entirely different compound; it is an alternative prodrug form (delivery mechanism) for the same molecule – tenofovir – that composes TDF. (See AA#2.)

12. Admit only insofar as the Phase III clinical trials and data sufficient to approve TAF did not exist at the time Gilead announced publicly that it was discontinuing TAF development precisely because Gilead chose not to generate that data as part of a strategy whereby TAF's development and entry into the market would be deliberately delayed until 2015. (See AA## 11-13,15,17-19.)

13. Admit in part and deny in part. Deny to the extent it implies Gilead did not have the data to know TAF was safer or better than TDF in the early 2000s as that data existed by as late as the end of 2002. Deny as to Gilead electing to restart its development of TAF in 2010; the decision to restart development of TAF had actually been made in 2003 when Gilead formulated the franchise extension strategy and carried implemented it almost exactly as prescribed. (See AA##11-13,15,17-19.)

14. Deny.

15. Admit.

16. Deny.

17. Deny.

18. Deny. Gilead did not just fail to release the data from GS-120-1101, it actively suppressed it. (7App.2156-2157,2196,2392-2193.) While the researchers who performed GS-120-1101 wanted to publish this data, the Company felt that doing so would create frustration in the medical community about why a drug that could lower human exposure to toxic tenofovir was not being brought to market. (*Id.*) Instead of releasing the data, Gilead decided any communication about TAF should reflect

appropriate "commercial messaging" that emphasized the excellence of TDF's safety profile and downplayed the comparative superiority of TAF. (*Id*.) Gilead all but admitted this when it finally did present the GS-120-1101 data in 2011 and Dr. Milligan stated that Gilead did not release the data in the early 2000s because having data that showed TDF might not be the safest product available would harm the Company's ability to successfully launch and establish TDF in the market. (7App.2387-2395.)

19. Admit in part and deny in part. Deny that Plaintiffs argue they have only a viable design-defect claim. Plaintiffs also separately assert they have viable ordinary negligence claims premised on Gilead's failure to exercise reasonable care to avoid foreseeable injuries by deliberately delaying TAF as it did. (10App.3010.)

20. Admit in part and deny in part. It is admitted only that Gilead did not and does not seek an exception to California Civil Code section 1714 and is therefore subject to the general duty of reasonable care without limitation or restriction.

21. Deny.

22. Deny.

23. Deny.

24. Deny.

25. Admit only as of the time of the time the Petition was filed.

26. Admit.

27. Admit in part and deny in part. Deny Gilead's mischaracterization of the motion *in limine*. Admit Plaintiffs are not claiming nor proceeding on a theory that TDF was "defective" as that term is used as a matter of law.

28. Deny.

29. Deny.

30. Deny.

31. Deny.

32. Deny.

33. Deny.

34. Deny. The issue is not solely what the GS-120-1101 study indicated about TAF, so much as what it revealed about TDF. In fact, the record shows that GS-120-1101 was suppressed because Gilead feared it would cast doubt on the safety of TDF, which was causing thousands of injuries, and thus turn off prescribers from choosing it for their patients. (7App.2156-2157,2196,2392-2393.) This is material information that was withheld from patients for the express purpose of continuing to keep them on TDF as opposed to another HIV drug. Gilead confirmed as much through Dr. Milligan's statements when it resumed TAF development and struggled to explain why it previously stopped development. (7App.2387-2395.)

35. Deny.

36. Deny.

37. Deny.

38. Deny.

39. Deny.

40. Deny.

41. Deny.

PRAYER

WHEREFORE, Real Parties in Interest and Plaintiffs pray that this Court:

1. Deny the Petition;
2. Award Plaintiffs costs incurred in this proceeding; and
3. Award such other and further relief as this Court deems just and proper.

Dated: September 19, 2022

GRANT & EISENHOFFER P.A.

KERSHAW, COOK & TALLEY, P.C.

JENNER LAW, P.C.

SCHNEIDER WALLACE COTTRELL KONECKY LLP

MOSKOVITZ APPELLATE TEAM

ESNER, CHANG & BOYER

By: *s/ Holly N. Boyer*
Holly N. Boyer
Attorneys for Plaintiffs and Real Parties in Interest

VERIFICATION

I, M. Elizabeth Graham, declare as follows:

I am licensed to practice law in the State of California and one of the attorneys of record for Real Parties in Interest and Co-Liaison Counsel for Plaintiffs. I have read the foregoing Return to Petition for Writ of Mandate and know its contents. The facts alleged in this Return are within my own personal knowledge based upon a review of the documents filed in the Respondent Court's records.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on September 19, 2022, at New Orleans, Louisiana.

/s/ M. Elizabeth Graham

M. Elizabeth Graham

MEMORANDUM OF POINTS AND AUTHORITIES

I.

PLAINTIFFS' THEORY OF NEGLIGENCE

Plaintiffs' theory of negligence is that Gilead owed Plaintiffs a duty to exercise reasonable care not to cause foreseeable injury to the users of its products. Gilead's decision to place profits over people when it deliberately delayed the development and availability of TAF breached that duty, causing thousands of individuals unnecessary harm. As detailed below, numerous courts as well as the California Legislature support the existence of such a duty of ordinary care as against manufacturers like Gilead. (See *Hasson,* 19 Cal.3d at pp. 540-544; *Brown v. Superior Ct.* (1988) 44 Cal.3d 1049, 1061; *Conte v. Wyeth, Inc*. (2008) 168 Cal.App.4th 89, 102; *Scott v. C.R. Bard, Inc.* (2014) 231 Cal.App.4th 763; *Hernandez, supra,* 28 Cal.App.4th at pp. 1802, 1826-1828; *Lunghi v. Clark Equipment Co.* (1984) 153 Cal.App.3d 485, 494; *T.H. v. Novartis Pharms. Corp.* (2017) 4 Cal.5th 145, 163-165; *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 63–65; *Love v. Wolf* (1964) 226 Cal.App.2d 378, 394-396; see also *Ileto v. Glock Inc.* (9th Cir. 2003) 349 F.3d 1191, 1201.) The allegations and evidence further demonstrate that Gilead undertook exclusive control over tenofovir-based antiretroviral medications and thus assumed a duty to act reasonably in this undertaking. (*Artiglio v. Corning Inc.* (1998) 18 Cal.4th 604, 613-616; *Scott,* 231 Cal.App.4th at pp. 774–76.)

To be absolutely clear, Plaintiffs are not pursuing a claim for negligent design defect. Rather, their negligence theory is rooted in Gilead's conduct separate and apart from the design of the TDF-based medications. Whether or not TDF was defective in design, manufacturer or warning is thus "extrinsic" to the negligence alleged, and the theories do not "merge" under California law. (See *T.H.*, *supra,* 4 Cal.5th at p. 180; *Lambert v. General Motors* (1998) 67 Cal.App.4th 1179, 1185.)

II.

PLAINTIFFS' NEGLIGENCE CLAIM IS CONSISTENT WITH LONGSTANDING CALIFORNIA POLICY

"A plaintiff in any negligence suit must demonstrate 'a legal duty to use due care, a breach of such legal duty, and [that] the breach [is] the proximate or legal cause of the resulting injury.'" (*Kesner v. Superior Court* (2016)1 Cal.5th 1132, 1142.) "'A duty of care may arise through statute' or by operation of the common law.'" (*Sheen v. Wells Fargo Bank, N.A.* (2022) 12 Cal.5th 905, 920–21.) As alleged, a duty exists here under Section 1714 as well as by operation of common law.

As articulated in the seminal *Rowland* decision, the "***basic policy of this State*** set forth by the Legislature in section 1714 of the Civil Code" is that liability is imposed for injury occasioned to another by his want of ordinary care or skill. (*Rowland,* 69 Cal.2d at pp. 118-119 (emphasis added); see also *Tarasoff v. Regents of Univ. of California* (1976) 17 Cal.3d 425, 434 [quoting same].) "'[W]henever one person is by circumstances placed in such a position with regard to another ... that if he did not use ordinary care and skill in his own conduct ... he would cause danger of injury to the person or property of the other, a duty arises to use ordinary care and skill to avoid such danger.'[Citation.]" (*Id.*)

"Generally speaking, all persons have a duty to take reasonable care in their activities to avoid causing injury, though particular policy considerations may weigh in favor of limiting that duty in certain circumstances." (*Brown v. USA Taekwondo*, *supra,* 11 Cal.5th at p. 209, citing Civ. Code, § 1714 and *Rowland, supra,* 69 Cal.2d 108.) As explained in *Rowland* and echoed in numerous California Supreme Court decisions thereafter: "Although it is true that some exceptions have been made to the general principle that a person is liable for injuries caused by his failure to exercise reasonable care in the circumstances, it is clear that in

the ***absence of statutory provision declaring an exception*** to the fundamental principle enunciated by section 1714 of the Civil Code, ***no such exception should be made unless clearly supported by public policy***." (*Rowland*, at p. 112 (emphasis added); *Cabral, supra,* 51 Cal.4th at p. 774; *Vasilenko v. Grace Fam. Church* (2017) 3 Cal.5th 1077, 1083 [quoting same]; *S. California Gas Leak Cases, supra,* 7 Cal.5th at p. 398.)

Despite a substantial body of case law on the two-step analysis of duty, where the court first considers whether a duty exists under Section 1714 or some other source, and then, second, looks to the *Rowland* factors to determine whether a categorical exception should be carved out for a certain category of defendants, Gilead argues that the court here erred in *imposing* a "radical" "*newly-minted duty*" against it. (Pet. at 28.)

Just as Gilead does here, the defendant in *Cabral*, *supra,* did not grasp the appropriate legal framework for the analysis of duty in a negligence action. (*Cabral, supra*, 51 Cal.4th at p. 783.) In that case, the defendant (Ralph's) argued "*creating* a common-law duty to avoid stopping near a freeway for nonemergencies would adversely impact roadway safety" and neither foreseeability nor public policy support the imposition of such a duty. (*Id*. at pp. 783.) The Supreme Court responded: "This argument materially misstates the issue." (*Id*.) "The question is not whether a *new duty* should be created, but whether an *exception* to Civil Code section 1714's duty of exercising ordinary care in one's activities, including operation of a motor vehicle, should be created." (*Id*. at p. 783.)

Bettencourt v. Hennessy Indus., Inc. (2012) 205 Cal.App.4th 1103 is likewise instructive on this point. There, in an opinion issued by Division five of this District, the Court reversed a court's order granting judgment on the pleadings on strict liability and negligence claims against Hennessy, a manufacturer of a machine designed to grind asbestos-containing brake pads. Pertinent to the analysis here, Hennessy argued that separate from the

claim for strict liability, there could be no negligence cause of action because "no duty of care exists." (*Id*. at p. 118.) "In Hennessy's view, the foreseeability of the harm is *insufficient to give rise to a duty of care*, and policy reasons preclude imposition of such a duty." (*Id*. (emphasis added).) Division five aptly noted: "Initially, *we question Hennessy's framing of this issue*." (*Id*. emphasis added).) "Under established California law, a manufacturer already owes a duty of care to foreseeable users of its product. [Citations.]" (*Bettencourt,* 205 Cal.App.4th at pp. 1117–19.) **"'Because the general duty to take ordinary care in the conduct of one's activities (Civ.Code, § 1714, subd. (a)) *indisputably applies' to product manufacturers*, 'the issue is ... whether a categorical exception to that general rule should be made' in these circumstances**. (*Cabral*, []at p. 774, [].) Such an exemption is appropriate 'only when foreseeability and policy considerations justify a categorical no-duty rule....' (*Id*. at p. 772, [].)" (*Id*. (emphasis added).) The Court then refused to recognize such a categorical exception. (*Id*. at p. 119 ["On the facts plaintiffs allege, Hennessy has failed to justify imposition of a categorical no-duty rule."].)

These decisions illustrate that Gilead's "framing of the issue" here fails to appreciate that it absolutely owed a duty of reasonable care to Plaintiffs. Indeed, as noted by the Superior Court below, "***Gilead does not dispute the existence of its duty of care***." (MPA at pp. 12-19; Reply at pp. 5—8.) To the extent Gilead believes that there is no cognizable negligence claim because it does not owe a legal duty or the duty as framed by Plaintiffs, Gilead does not brief such an argument as necessary to carry its initial burden." (10App.3247 (emphasis added).) Instead, Gilead argues, unsuccessfully, that California does not recognize non-defect claims of ordinary negligence against product manufacturers. But absent any existing recognized exception to section 1714, this is really a *Rowland* argument.

However, and as held by the Superior Court here, Gilead has not "undertaken an analysis of the *Rowland* factors to establish that it did not owe the alleged duty of care under Civil Code section 1714." (10App. 3247.) Having failed to properly frame the issue in its motion for summary judgment, or even in its Petition before this Court, the order denying summary judgment should thus be affirmed.

A. California Courts Have Long Recognized The Viability of Non-Defect Negligence Claims Against Product Manufacturers.

The judiciary's recognition of product liability theories against manufacturers based on "defects" in the product does not obviate all other forms of negligence liability. As recognized by the court here in denying Gilead's motion for summary judgment, Gilead cites no authority to support such blanket immunity for product manufacturers and indeed the law provides just the opposite.

> **In actuality, *Gilead's argument is contrary to California law:* Plaintiffs may proceed on a theory of negligence and are not required to proceed on a product liability theory.** (*Conte v. Wyeth, Inc*. (2008) 168 Cal.App.4th 89, 102 [distinguishing theories of liability, finding "no logical or legal inconsistency between allowing the suit for negligence and disallowing the suit for strict products liability"; accord *T.H, supra,* 4 Cal.5th at pp. 162, 175-80 [rejecting argument that liability should not exist based on out-of-state authority and practices in foreign jurisdictions]; *Milwaukee Elec. Tool Corp. v. Super. Ct.* (1993) 15 Cal.App.4th 547,557; *Brown v. Superior Ct.* (1988) 44 Cal.3d 1049, 1061; *Scott v. C.R. Bard, Inc.* (2014) 231 Cal.App.4th 763, 774.) While it may be true that many plaintiffs proceed on a strict products liability theory-a theory offering plaintiffs a lesser burden of proof--it is simply not the case that a plaintiff *must* proceed on a products liability theory as negligence is available in California. (*Ibid.*)

(10App.3246 (emphasis added).)

Conte, supra, is instructive. There, the plaintiff alleged that she suffered injury as a result of her long-term consumption of a generic prescription drug and brought an action against the name-brand manufacturer on the ground that the warnings provided failed to adequately warn of the dangers. Among her claims against the name-brand manufacturer was a claim for negligent misrepresentation. The lower court granted summary judgment in favor of the manufacturer finding that it owed no duty to individuals who take only generic versions of its products. The Court of Appeal reversed.

The Court began by noting that "[a]s a preliminary matter, *we reject Wyeth's syllogism premised upon product liability doctrine* that (1) this is merely a products liability lawsuit disguised as an action for fraud and misrepresentation; and (2) Conte cannot prevail on a strict products liability claim because Wyeth did not manufacture or sell the product that allegedly caused her injury; so (3) Conte loses. The conclusion would be sound were Conte in fact pursuing a cause of action against Wyeth for strict products liability. *But she is not*." (*Id*. at p. 101.) The Court explained that the plaintiff "does *not* allege that Wyeth is strictly liable because inadequate warnings rendered *its product* unreasonably dangerous," but "[r]ather, she charges that Wyeth failed to use due care when disseminating its product information." (*Id*.)

After highlighting that negligence and strict products liability "are separate and distinct bases for liability," the Court explained that the manufacturer's reliance on strict product liability cases to argue that a plaintiff in a "products liability case must prove that the defendant made or sold the allegedly defective product that causes injury *sheds no light on the issue presented for our consideration*." (*Conte*, 168 Cal.App.4th at p. 102.) The Court explained:

> Our decision today *is rooted in common sense and California common law.* We are not marking out new territory by recognizing that a defendant that authors and disseminates information about a product manufactured and sold by another may be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on that information and the product causes injury, even though the defendant would not be liable in strict products liability because it did not manufacture or sell the product. [Citation] **We perceive *no logical or legal inconsistency between allowing the suit for negligence and disallowing the suit for strict products liability.***

(*Id*. at p. 103 (emphasis added).)

Indeed, the Court engaged in a *Rowland* analysis to determine whether a categorical exception should be recognized alleviating name-brand manufacturers from a duty of care to patients who take a generic version of the drug in reliance on the name-brand manufacturer's information. (*Id*. at p. 103.) After considering such factors, the Court held "[w]e are not persuaded that the application of these factors supports *a departure in this case form the general rule that all persons have a duty to use ordinary care to prevent harming others*." (*Id*. at p. 106 (emphasis added).)

Likewise, the analysis in *T.H.*, *supra*, 4 Cal.5th 145, supports the viability of negligence claims against drug manufacturers - *not limited in scope* by principles of strict products liability. In that case, the Supreme Court began its analysis of duty by once again citing Section 1714. (*Id*. at p. 163.) After noting that a manufacturer must act reasonably in warning physicians of the risks known or reasonably known to the manufacturer, the Court turned to an analysis of *Rowland* "[t]o determine whether to create an exception to a brand-name drug manufacturer's duty to warn" and ultimately concluded that no such policy justification existed to limit the duty owed. (*Id*. at pp. 164-165.) The Court's analysis of the *Rowland*

factors highlights the negligence at issue – the failure to exercise reasonable care and the foreseeable harm that failure caused Plaintiffs. While concerned with "warning liability," the theory is rooted in principles of ordinary negligence.

Not surprisingly, Gilead attempts to distinguish *Conte* and *T.H.* in its Petition, though it succeeds only in misrepresenting the record and the decisional law. According to Gilead, "*Conte* is not a design-defect case nor is it a free-floating negligence case. And nothing about *Conte* supports the radical theory advanced by Plaintiffs here that people injured when using a product hold the manufacturer liable *without proving that the product that allegedly injured them is defective*." (Pet. at 48). Similarly, Gilead comments that under *T.H.*, "California law makes clear that, 'in the context' of a plaintiff's allegation of injury from a product, this general duty in Section 1714 takes on a specific form: the duty embodied by the products-liability caselaw." (Pet. at 39,48.)

Notwithstanding that *Conte* actually held the exact opposite of Gilead's interpretation, or that nothing whatsoever in *T.H.* supports the merger of Section 1714 and whatever Gilead means by "products-liability caselaw," the most glaring fault in Gilead's analysis lies with its complete failure to even identify, let alone discuss, the long history of California decisions that have repeatedly and expressly rejected the notion that a finding of "no product defect" necessarily precludes a finding of negligence by a product manufacturer. (See *Scott*, *supra*, 231 Cal.App.4th 763; *Hernandez*, *supra*, 28 Cal.App.4th at pp. 1802, 1826-1828; *Lunghi*, *supra*, 153 Cal.App.3d at p. 494; *Hasson*, *supra*, 19 Cal.3d at pp. 540-544.)

Beginning in 1977 with the Supreme Court's decision in *Hasson*, *supra*, California courts have consistently dismissed product manufacturers' arguments that the development of law imposing liability "… based upon a 'defect' of design or manufacture encompasses all of the

conceptual basis which would give rise to a traditional common law liability for negligence of a manufacturer." (*Hasson*, at p. 541). By arguing that "[i]n effect, the newer law subsumes the old," product manufacturers like that in *Hasson* have contended that a "… finding that there was no 'defect' obviates any finding of 'negligence,'" or, stated differently, "whenever there is a finding of an absence of a 'defect' … all further inquiry is ended." (*Id*.) But according to the Supreme Court, such is not the case, and " … ***a failure to find a 'defect' … would not necessarily preclude all liability***" for a product manufacturer defendant. (*Id*. at pp. 542) (emphasis added).)

Applying the Supreme Court's holding in *Hasson*, subsequent cases like *Hernandez*, *supra,* have reiterated that a finding that the product " … had no design defect [does] not preclude a finding [the defendant] was nonetheless negligent," especially where the plaintiff presents "evidence on negligence quite apart from [a] design issue …" (*Hernandez*, *supra*, 28 Cal.App.4th at p. 1827 (quoting *Lunghi*, *supra*, 153 Cal.App.3d at p. 494); see also *Lambert*, *supra* [recognizing negligence and negligent design do not merge to require a showing of "defect" when there is evidence of negligence outside the design of the product itself]; *Baker v. Cottrell, Inc.* (2020) 831 Fed.Appx. 246, 248 [applying California law to reject the notion that a finding of "no defect" precludes negligence liability where the verdict rested on a theory other than the design of the product].) In fact, when the plaintiff shows that a product manufacturer "had not met the standard of reasonable care," by, among other things, failing to do "everything reasonably within its power to prevent injury," liability is not inconsistent with "a finding that the product's design was not defective." (*Hernandez*, at pp. 1827-1828, citing *Lunghi*, *supra*; *Balido v. Improved Machinery, Inc.* (1972) 29 Cal.App.3d 633, 649.)

Scott, supra, is also instructive. There, the plaintiff sued alleging strict product liability, negligence, fraud and breach of warranty. (*Scott*, *supra*, 231 Cal.App.4th at p. 771.) During trial the court directed verdict in favor of the defendant on the manufacturing defect, fraud and breach of warranty claims. The jury then returned a verdict against plaintiff on the failure to warn claim. However, the jury found the manufacturer to be negligent and awarded damages. (*Id*. at p. 772.) On appeal, the manufacturer argued that the negligence theories (negligent design, negligent assumption of the training of physicians as to the use of its product and negligent misrepresentation to the doctor that prescribed the product) should never have gone to the jury.

Relevant to the analysis here, the jury was presented with all three negligence theories and returned a verdict without specifying which theory it relied on. (*Id*. at pp. 777-778.) Similar to the arguments raised by Gilead, the manufacturer argued that not all three theories were viable and thus reversal was required since there was no way to tell if the jury relied on the legally improper theories. (*Id*. at p. 778.) The Court of Appeal rejected the argument finding that *all three negligence theories* were "legally valid" and thus sufficient to support the verdict. (*Id*.) Because two of the theories concerned "non-defect" claims, the opinion dispels the false premise that such liability is exempted as against product manufacturers.

At bottom, all of these decisions are fatal to Gilead's Petition because they unequivocally recognize a "claim for negligence *distinct* from any finding that the product is itself defective." [3] As recognized by the

[3] Throughout its Petition and before the Superior Court, Gilead relies extensively on a soundbite from a Michigan state court - "'Like the courts in every other state, whether a suit is based upon negligence or implied warranty, … the plaintiff must, in every case, in every jurisdiction, show that the product was defective.'" (See Pet. at 27,43,48; 10App.3147,3160; citing *Prentis v. Yale Mfg. Co.* (Mich. 1984) 365 N.W.2d 176, 181-82.)

Superior Court here, "Plaintiffs may proceed on a theory of negligence and are not required to proceed on a product liability [i.e. defect] theory." (10App.3246.)[4]

B. Gilead's Claim that the Duty Owed by Product Manufacturers is *Limited* Only to Theories Alleging that the Product is Itself Defective is Entirely Fabricated.

In support of its argument that a manufacturer may be liable in negligence only where it is alleged that the product is itself defective, Gilead represents that the "general duty in Section 1714" is limited in product liability actions. (Pet. at 39,43.) Gilead relies nearly exclusively on the Supreme Court decision in *Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 513. *Merrill* in no way supports Gilead's representation that

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Setting aside the fact that *Prentis* involved a case alleging liability for "defective design" only, and that Michigan – unlike California – has a Product Liability Act that legislatively subsumes all causes of action into one requiring the showing of a "defect," the decision of another state concerning its own negligence liability is unpersuasive when looking at California's codification of the "basic policy of this State" and the seminal decision permitting a categorical exception. (See *Rowland,* 69 Cal.2d at pp. 118-119; Civ. Code § 1714(a).) As held by the court here, such out of state authority should not govern the viability of a negligence claim under California law. (See 10App.3245 ["citing *T.H., supra,* 4 Cal.5th at pp. 162, 175-80, [rejecting argument that liability should not exist based on out-of-state authority and practices in foreign jurisdictions]"].)

[4] See also *Ileto v. Glock Inc*. (9th Cir. 2003) 349 F.3d at p. 1201 [discussed in detail below]; *In re JUUL Labs, Inc., Mktg., Sales Pracs., & Prod. Liab. Litig.* (N.D. Cal. 2020) 497 F. Supp. 3d 552, 645–51 [nuisance claims], 654-666 [negligence claims] [in action brought by school districts against defendant manufacturers who created, sold, distributed, or sold supplies for e-cigarettes, Court denied demurrer to California non-defect negligence and nuisance claims; "[t[he allegations here do not concern the JUUL product *itself*, but rather the alleged consequence of JLI's conduct. Put differently, the public nuisance claims are premised on JLI's aggressive promotion of JUUL to teens and efforts to create and maintain an e-cigarette market based on youth sales, *not on any alleged defect in JUUL products*."].)

the only negligence claims that may be brought against a product manufacturer are those alleging that the product is *itself* defective.

In *Merrill*, the plaintiffs, survivors and the representative of victims who were killed when an individual entered a law firm and fired assault weapons, brought an action for negligence against the gun manufacturer. In reviewing the lower court's order granting summary judgment in favor of the manufacturer (and the court of appeal's decision reversing that ruling), the California Supreme Court began by highlighting the duty arising under Section 1714. "[W]e '***begin always with the command of … section 1714,*** subdivision (a): [reciting text]." (*Merrill,* 26 Cal.4th at p. 477 (emphasis added).) The Court then noted that "exceptions" to the general rule of duty do exist and explained: "Some are established by the Legislature through enactment of statutes. Others are judicially established where 'clearly supported by public policy.'" (*Id*.)

The Court next turned its analysis to a ***legislatively created exception*** to design defect claims involving firearms that stated, "[i]n a products liability action, no firearm or ammunition shall be deemed defective in design on the basis that the benefits of the product do not outweigh the risk of injury posed by its potential to cause serious injury, damage, or death when discharged." (*Id.*, at p. 478, citing former Civ. Code § 1714.4.) The issue before the Court was whether the plaintiff's negligence claims fell within the ambit of this statutory exception. (*Id*. at pp. 478-482.) In its analysis of the statutory term "products liability action," the Court held that the Legislature intended to adopt both strict liability and negligent design defect claims. (*Id*. at pp. 479-480.)

The Court then considered the theories of negligence alleged and argued by the plaintiffs and held that the ***statutory*** exception applied to bar Plaintiffs' negligence action. (*Id.* at pp. 480-481.) According to the Court, although the complaint included allegations of negligent marketing, selling

and manufacturing, all of the negligence theories rested on an alleged *dangerous design* of the firearm. (*Merrill*, 26 Cal.4th at p. 473-474.) As such, the claims involved a "products liability action" alleging *design defect* in firearms and thus fell within the specific statutory contours of the exception prescribed by Section 1714.4.

Although Gilead cites *Merrill* more than any other case in its Petition, nothing in *Merrill* supports Gilead's position that the *only* negligence claims permitted against a product manufacturer are those alleging a defect in the product. *Merrill* concerned a firearm industry-specific statutory exemption for strict liability and negligent *design defect claims* – this is *not* a design defect claim and there is *no* statutory exemption whatsoever. What is more, the statutory exemption at issue in *Merrill* no longer exists. [5] Even Gilead's discussion of *Merrill* and the purported parallels here are specious. (Pet. at 43-44.)

Gilead represents that "[j]ust as here," the plaintiffs in *Merrill* tried to recast their design defect claim as an ordinary negligence claim by

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[5] Notably, the California legislature *repealed Section 1714.4* shortly after and in direct response to the Supreme Court's decision in *Merrill*. (See S.B. 682, 2001-2002 Reg. Sess. (Cal. 2002) ["This bill deletes the existing code section providing statutory protection from liability for manufacturers and sellers of firearms. The bill is intended to address the recent California Supreme Court decision, in *Merrill v. Navegar*, holding that California's existing statutory language barred liability for the manufacturer of the guns used in the infamous 101 California Street massacre in a suit brought under a theory of common law negligence. Status: Chapter 913, 2002."].) The bill also added language to Section 1714 to expressly permit negligence actions against gun manufacturers: "The design, distribution, or marketing of firearms and ammunition is *not exempt* from the duty to use ordinary care and skill that is required by this section." (See Civ. Code § 1714(a).) Thus, if anything the Legislature's response to *Merrill* underscores the sanctity of the *presumed general duty* owed by all product manufacturers under Section 1714 and California's reluctance to carve out exceptions immunizing negligence claims against them.

simply focusing on the manufacturer's allegedly "negligent conduct." (*Id.*) Gilead appears to suggest that in *Merrill*, and supposedly here, the plaintiffs argued that their claim focused not on the product but on the conduct of the manufacturer – and thus was a negligence claim outside the reach of the statutory exception. (*Id.*) While it is not even clear that was the argument advanced by the plaintiffs in *Merrill* – it is in no way an argument advanced by Plaintiffs here. Plaintiffs appreciate that where a plaintiff alleges a claim for strict liability in *design defect*, the plaintiff must prove that the product is defective. Further, and assuming the plaintiff pursues a parallel negligent *design defect* claim, the plaintiff must prove that the product is defective *and* the manufacturer's conduct fell below the standard of care. The problem for Gilead is that this is *not* Plaintiffs' claim.

Throughout its Petition and below, Gilead conflates principles of strict products liability with claims of ordinary negligence. While a defect in the product is a predicate to any claim for strict products liability, the same is not true for all negligence claims against a manufacturer. In other words, a plaintiff pursuing a claim for manufacturing defect, design defect or warning defect may do so under either a strict liability or negligence theory – but this principle in no way limits the universe of negligence claims that can be asserted against a product manufacturer.

While strict liability requires that there be a defective product, no such requirement exists for all negligence claims against product manufacturers. Instead, and what Gilead repeatedly exploits, is that where a plaintiff *alleges a defect* in design, manufacturer or warning, under *both* a theory of strict product liability and negligence – the plaintiff necessarily must prove that the product is defective under both theories. (See *Chavez v. Glock, Inc.* (2012) 207 Cal.App.4th 1283, 1303 ["A design defect exists when the product is built in accordance with its intended specifications, but the design itself is inherently defective."].) While this seems logical given

that the predicate to both theories is a defective product, the notion does not extend so far as to exempt manufacturers from all ordinary negligence liability for *non-defect* claims.

As evidence of its apparent confusion (or worse deliberate misrepresentation) concerning the viability of non-defect negligence claims against manufacturers, Gilead fails to acknowledge that its cited authority almost exclusively concerns strict liability doctrine. (See Pet. at 43, citing *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335 as holding "Manufacturers are not insurers for customers' injuries—there is no '*absolute* liability' just because a product causes injury.") The full quote from *O'Neil* reveals that its discussion concerns the *doctrine of strict liability* – not ordinary negligence. "'From its inception, ... ***strict liability*** has never been, and is not now, *absolute* liability. As has been repeatedly expressed, *under strict liability* the manufacturer does not thereby become the insurer of the safety of the product's user. [Citations.]'" (*O'Neil,* at p. 362, citing *Daly v. Gen. Motors Corp.* (1978) 20 Cal.3d 725, 733.) Likewise, in *Daly*, where the quote originated, the Court highlighted the fact that strict liability is different in kind than negligence; "***the concept of strict products liability was created and shaped judicially***. In its evolution, the doctrinal encumbrances of contract and warranty, and the traditional elements of negligence, were stripped from the remedy, and *a new tort emerged* which extended liability for defective product design and manufacture beyond negligence but short of absolute liability." (*Daly*, at p. 733 (emphasis added).)

As has been repeatedly recognized by the California Supreme Court and Courts of Appeal, strict liability is a "distinct doctrine" separate and apart from negligence liability. (See *Kim v. Toyota Motor Corp.* (2018) 6 Cal.5th 21, 37; see also *Conte*, *supra*, 168 Cal.App.4th at pp. 100–101 ["***Negligence and strict products liability are separate and distinct bases***

for liability that do not automatically collapse into each other because the plaintiff might allege both …."].) Thus, the bases for liability are separate and distinct. The fact that the judicially created doctrine of strict product liability rests on a finding that the product is itself defective in no way limits or otherwise narrows the available theories of negligence against a manufacturer.

Nothing in *Merrill* alters this analysis. The Ninth Circuit's decision in *Ileto*, *supra*, 349 F.3d 1191, which followed the *Merrill* decision, acutely highlights the flawed reasoning espoused by Gilead here. Dealing with the same statutory exception for design defects involving firearms, the issue in *Ileto* was whether the negligence and nuisance claims brought by the plaintiffs there were in fact claims falling within the Legislatively created immunity. (*Id*. at pp. 1200-1202.) The Ninth Circuit held that the allegations sounded in ordinary negligence – *not* design defect.

> In *Merrill*, distribution claims did not stand alone; references to "distribution" were to *distribution of a defective product*. Here, as the district court emphasized, "Plaintiffs ... do not allege that Glock is negligent in distributing its firearms to the general public. Rather, they contend that Glock's distribution scheme specifically targets criminal users." [Citation] **Unlike the *Merrill* plaintiffs, who alleged that the gun manufacturers' decision to distribute the guns in question to the general public *was negligent in light of the guns' alleged defective design features*** and therefore was "simply a reformulated claim that the weapon, as designed, fails the risk/ benefit [products liability] test," *Merrill*, 110 Cal.Rptr.2d 370, 28 P.3d at 126, ***here plaintiffs focus on the negligent distribution of a non-defective product***. The focus is on the defendants' *affirmative actions in distributing their products to create an illegal secondary market* for guns that targets illegal purchasers.

(*Id*. at p. 1201 (emphasis added).) The Court explained "this is an action that alleges negligence and public nuisance claims; it does not allege that

the guns in question were defectively designed or manufactured or that the defendants failed to affix an adequate warning on the guns." (*Id.*)[6]

C. Gilead Has Never Challenged That It Owes a Duty of Care Arising From Its Undertaking to Exclusively Develop, Manufacture and Sell Tenofovir-Based Pharmaceuticals.

Furthermore, and independent of the viability of Plaintiffs' claim for negligence as arising under Section 1714, the allegations and evidence here support the common law theory of negligent undertaking, which Gilead has never attacked. "A defendant who enters upon an affirmative course of conduct affecting the interests of another is regarded as assuming a duty to act, and will be liable for negligent acts or omissions [Citations], because one who undertakes to do an act must do it with care. [Citations]. As Prosser states: 'Where performance clearly has begun, there is no doubt that there is a duty of care.' (Prosser, Handbook of the Law of Torts (4th ed. 1971) § 56, p. 346.)" (*Bloomberg v. Interinsurance Exch.* (1984) 162 Cal.App.3d 571, 575.)

Courts have recognized application of this doctrine in the context of drug and medical device companies. (See *Scott, supra,* 231 Cal.App.4th at pp. 774–76 [theory that manufacturer of prescription medical device undertook a duty to train physicians in using its medical device and allegedly failed to do so reasonably causing the plaintiff harm properly submitted to the jury]; *Artiglio*, *supra*, 18 Cal.4th at pp. 613-616.)

In *Artiglio,* recipients of silicone gel breast implants manufactured by Dow Corning brought an action for negligence against Dow Corning's parent manufacturer – Dow Chemical. Although Dow Chemical never made or sold silicone implants, the plaintiffs pursued an action against Dow

[6] The Ninth Circuit's decision in *Ileto* itself also recognizes the viability of non-defect ordinary negligence claims against product manufacturers.

Chemical under a theory of negligent undertaking because it performed research concerning silicone toxicology and supplied such research to the manufacturer. (*Artiglio*, at pp. 614-617.) According to the plaintiffs, by performing toxicological research with regard to silicones for the manufacturer, Dow Chemical *owed a duty to act reasonably in this undertaking* and is liable for any alleged failure to do so. (*Id*. at pp. 613-616.) While the Court accepted that based on the record Dow Chemical undertook to conduct and report certain silicone toxicology research, and "obviously" such an undertaking "at least theoretically implicates the well-being and protection of potential patients," the Court held the duty at issue is not indefinite. (*Id*. at pp. 616-617.) Based on the facts before it, and specifically the delay between the research conducted and the actual manufacture and marketing of the implants, the Court declined to find that Dow Chemical could be liable under a negligent assumption theory.

The Court's analysis highlights the availability of an ordinary negligence claim – where regardless of any defect alleged in the product, the defendant must act reasonably in the duty assumed. Had the evidence in *Artiglio* supported the doctrine's application, Dow Chemical would have been under *a duty of care to act reasonably* in conducting its research concerning silicone toxicity. (See also *Scott,* 231 Cal.App.4th at pp. 772, 774–76 [drug company owed duty to act reasonably in training physicians as to the non-defective product].)

Here, as alleged in the complaint and demonstrated by the evidence, in addition to Section 1714, Gilead owed a duty to act reasonably in its decision to deliberately delay the release of TAF following TDF so as to maximize profits at the expense of exposing thousands of individuals with unnecessary harms given its affirmative conduct in monopolizing tenofovir-based antiretroviral compounds. (See 1App.68-71; AA#1-24.) Under this theory of negligence, a jury must decide not only the contours of the duty

assumed in its multi-billion dollar enterprise to monopolize the market in the treatment of HIV (to the explicit exclusion of all others), but also whether Gilead *exercised reasonable care* in its lucrative endeavor. (See *Artiglio*, 18 Cal.4th at pp. 615-616 [scope of a defendant's duty presents a jury issue when there is a factual dispute as to the nature of the undertaking]; *O'Malley v. Hosp. Staffing Sols.* (2018) 20 Cal.App.5th 21, 26-29 [triable issues of fact existed as to what defendant undertook to do, and whether it was done reasonably]; CACI 450C.)

Although specifically pled in the Master Complaint (1App.68-69), Gilead failed to challenge this negligence theory in its motion for summary judgment or in its Petition. As held by the Superior Court, Gilead's only challenge to the negligence claim was its mistaken contention that "a negligence claim is simply unavailable." (10App.3246 ["the Court observes that Gilead has not mounted any other challenge to Plaintiffs' ability to establish their ordinary negligence claim's essential elements"], 3247 ["Gilead does not otherwise contend that Plaintiffs cannot establish one or more elements of their negligence claim. Further, there are triable issues of material fact as to whether Gilead's conduct was negligent in light of its knowledge that TDF was toxic and that TAF did not carry the same risks as TDF. [Citations] Thus, the Court *cannot summarily adjudicate Plaintiffs' negligence claim*."].) The court highlighted that Gilead's motion for summary adjudication of the negligence claim attacked the entire claim for negligence– not an individual issue of law alleged within the claim. (10App.3248 [citing Code Civ. Proc. § 437c(t).)

Thus, in light of the failure to even address the allegations in the Master Complaint concerning Gilead's assumed duty, summary adjudication of the negligence claim could not be granted. Nor can summary adjudication of the negligence claim be issued on appeal as

Gilead never properly addressed this theory nor argued it before the Superior Court.

D. While Gilead Failed to Argue that a Categorical Exemption Should Be Recognized Here and Has Thus Waived the Issue, the *Rowland* Factors in No Way Justify a Limitation of Gilead's General Duty of Care.

As highlighted by the Superior Court, Gilead has not "undertaken an analysis of the *Rowland* factors to establish that it did not owe the alleged duty of care under Civil Code section 1714." (10App.3247.) Neither before the court nor in its Petition does Gilead engage in an analysis of the *Rowland* factors to justify a categorical exception to the duty owed.

According to its Reply to Plaintiffs' preliminary opposition here, "Gilead is not demanding an 'exception' from its duty of care, such that Gilead would need to resort to the California Supreme Court's decision in *Rowland v. Christian* (1968) 69 Cal.2d 108." (Reply to Prelim. Opp. at 20.) However, while Plaintiffs accept this representation and note Gilead's explicit waiver of any argument that a categorical exception should be made here, Gilead's Petition nonetheless spews policy arguments of inevitable doom should a duty be "recognized" here. (Pet. at 38,48.) Indeed, an entire section of Gilead's Petition is devoted to its argument that "[a]uthorizing liability for injuries caused by non-defective products would radically transform mass tort litigation, eviscerating decades-old protections in the common law and wreaking havoc in the pharmaceutical industry and beyond." (Pet. at 48-52.) Thus, although Gilead posits that it need not "resort" to a *Rowland* analysis, that is precisely what it seeks to do – yet,

without ever identifying the factors nor addressing the overwhelming policies that favor the existing duty owed. [7]

Gilead absolutely owed Plaintiffs a duty to act reasonably in its conduct and avoid causing Plaintiffs foreseeable harm by its conduct. It is in the context of breach that the reasonableness is defined. This is why the *Rowland* factors are considered at a "relatively broad level of factual generality" – to avoid usurping the role of the jury in an initial analysis of duty. (*Cabral*, 51 Cal.4th at p. 772-773.) As highlighted by the Supreme Court in *Cabral,* the duty of care owed is simply to *act reasonably*; what counts as reasonable under the circumstances is characteristically a question of breach. (*Id*.) Thus, acknowledging the existence of a duty to act reasonably in negligence is not synonymous with a finding of liability. (*Regents, supra,* 4 Cal.5th at p. 634.) As explained in *Cabral:*

> Indeed, one might ask under what circumstances Ralphs would have us recognize a duty of ordinary care in stopping alongside a freeway, if not in these. If stopping 16 feet from the traffic lanes exempts a driver from the duty of care, does the same hold for parking six feet from the lane? Six inches? If we are to create immunity for a truck driver stopping for a few minutes to have a snack, should we also do so for one who decides to sleep for hours by the roadside rather than pay for a motel room? Would the categorical exemption Ralphs seeks still apply if a tractor-trailer driver parked an inch from the traffic lanes, on the outside of a curve, leaving the rig there all night without lights? To ask these questions is to see why a categorical exemption is not appropriate. **The *duty of reasonable care* is the same under all these circumstances*;*** *what varies with the specific facts of the case is whether the defendant has breached that duty.* ***That*** **question, as discussed**

[7] Given Gilead's refusal to engage in a *Rowland* analysis, the record does not support such on appeal. (See *Conte, supra,* 168 Cal.App.4th at 106-108, 110 [noting similar deficiencies in the record before it to support a judicially created exception to duty].) For example, it is not even clear to whom Gilead argues a no-duty rule should apply – as its policy arguments reference *all* product manufacturers – not just drug manufacturers.

earlier, is generally one to be decided by the jury, not the court.

(*Cabral,* 51 Cal.4th at p. 784 (emphasis added)).

As explained above, "'[b]ecause the general duty to take ordinary care in the conduct of one's activities (Civ.Code, § 1714, subd. (a)) indisputably applies' to product manufacturers, 'the issue is ... whether a ***categorical exception*** to that general rule should be made" in these circumstances. (*Cabral* [] 51 Cal.4th 764, 774, [].) While the duty of reasonable care is specific to the circumstances of the individual case, exceptions to that duty are appropriate "only when foreseeability and policy considerations justify a categorical no-duty rule...." (*Id.* at p. 772, [].)" (*Bettencourt*, 205 Cal.App.4th at p. 1118.)

The *Rowland* factors generally fall into two categories – those concerning foreseeability and those that consider public policy. (*Kesner, supra*, 1 Cal.5th at p. 1145.) As detailed in the analyses undertaken by the courts in *Conte* and *T.H.*, both of which concern prescription drug manufacturers, application of these factors here in no way supports a categorical exception to the duty. With respect to foreseeability, there can be no meaningful dispute that such factors weigh in favor of the duty and against any categorical exception. Gilead *knew* people would unnecessarily suffer the injuries alleged as a result of Gilead delaying the development of TAF – which is exactly what happened. (*See Conte, supra,* 168 Cal.App.4th at 105-108; *T.H., supra,* 4 Cal.5th at pp. 166-167.) Moral blame, the policy of preventing future harm and the availability of insurance all likewise counsel against shielding manufacturers from a duty as alleged here. (*Conte,* at 106-111; *T.H.,* at pp. 168-180.)

The only factor argued by Gilead is the supposed *burden to Gilead* and potential consequences to the community should the duty not be relieved. But, and as held by the Superior Court, Gilead's "parade of

horribles" do not exist. (10App.3247 ["The Court also finds unpersuasive Gilead's parade of horribles [citation] because the hypotheticals are rooted in a misconstruction of Plaintiffs' claim and the specific facts alleged and many of these policy arguments."].) Significantly absent from every one of Gilead's fabricated hypotheticals is any indication the would-be defendant anticipated the harm.

According to Gilead, recognizing a negligence claim here would "stifle medical innovation and research" and "weaponize scientific discovery." (Pet. at 9,34,38.) Not so.[8] There is no support for such hyperbolic contentions. As was the case in *Conte*: "*We are unpersuaded by Wyeth's assertion that imposing liability would undermine the goal of preventing future harm because it would chill innovation in the pharmaceutical industry.* ***No evidence was introduced on summary judgment to support this supposition, much less to permit an informed balancing of such a risk against the harm to patients that might be prevented by recognizing a duty of care***." (*Conte*, 168 Cal.App.4th at p. 106 (emphasis added); see also *T.H.*, *supra,* 4 Cal.5th at pp. 170–72.)

In fact, this case shows the exact opposite of Gilead's supposed parade of horribles would result by allowing Plaintiffs to proceed under a negligence theory. Insulating a drug manufacturer from liability where it deliberately delays the availability of a safer drug — one that it is already developing — in order to reap financial benefit by manipulating its market exclusivity, all the while knowingly exposing individuals suffering from a life-threating disease to unnecessarily harm, does not advance society. (See *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1117 [in finding strict product liability claims for failure to warn applicable to drug

[8] This is not a duty to innovate case. Gilead had the drug already innovated and just chose to delay its release to manipulate its exclusivity and make more money.

manufacturers, the Court noted "we are unpersuaded by the argument, purportedly derived from our reasoning in *Brown*, that manufacturers of prescription drugs should be exempt from the strict liability duty to warn because they might otherwise refrain from developing and marketing drugs, including 'cutting-edge vaccines to combat human immunodeficiency virus (HIV)' and other diseases;" the Supreme Court noted that "unlike strict liability for design defects, strict liability for failure to warn does not potentially subject drug manufacturers to liability for flaws in their products that they have not, and could not have, discovered. Drug manufacturers need only warn of risks that are actually known or reasonably scientifically knowable."].)[9]

As noted by the Court in *T.H.*, "**time and again we have recognized how '"[t]he overall policy of preventing future harm is ordinarily served, in tort law, by *imposing the costs of negligent conduct upon those responsible*.**"' [Citations]." (*T.H.*, *supra*, 4 Cal.5th at pp. 168–69 (emphasis added).) The United States Supreme Court in *Wyeth v. Levine* (2009) 555 U.S. 555, also recognized that state common-law tort claims

[9] Here, and perhaps ironically, the drug at issue concerned treating the very serious disease of HIV and Gilead's decision to delay its development and release, thereby depriving individuals from its known benefits solely to line its own pockets. In *John B. v. Superior Court* (2006) 38 Cal.4th 1177, where the Supreme Court refused to limit liability for the negligent transmission of HIV only to those who have actual knowledge they are HIV positive, the Supreme Court relied on the seriousness of the disease to underscore the recognition of the duty, rather than to justify an exception under a *Rowland* analysis. (*John B.*, at p. 1196 ["Moreover, the gravity of the harm from HIV infection is a justification for imposing a greater duty of care on those who are infected (see Prosser & Keeton on Torts, supra, § 31, p. 171; Rest.2d Torts, § 293, com. c, p. 59) …"].) The analysis is appliable here where Gilead knew that its boardroom decision to deliberately delay TAF would injure thousands of patients suffering from HIV unnecessary – and only for the monetary gratification of Gilead.])

compliment drug regulation and add an "important, layer of consumer protection." (*Wyeth,* at pp. 578–79.)

There is simply no justification for immunizing drug manufacturers from liability under the despicable circumstances alleged here, nor is there social value in creating a bright line exception to liability that would apply to innumerable, unknowable future circumstances solely on the basis of a handful of Gilead's curated and self-serving hypotheticals.

III.

GILEAD'S ATTACK ON THE FRAUDULENT CONCEALMENT CLAIM LIKEWISE FAILS

Throughout this proceeding, Gilead contends it had no duty to disclose information about TAF to Plaintiffs and their doctors because as a matter of law such information was not material. Gilead argues the disclosure of such information about the safety of TAF would not have led doctors to avoid prescribing TDF to their patents including Plaintiffs. (1App.140-142[MSJ], 3151-3154[MSJ Reply ["Plaintiffs cannot show that Gilead disclosing information about TAF prior to its approval would have caused their doctors to stop prescribing TDF"]; Petition, 58-59, Reply, pp. 26-27.)

The Superior Court correctly rejected this argument, relying on established law supporting Plaintiffs' claim for fraud and concealment. (*see, e.g.*, *LiMandri v. Judkins* (1997) 52 Cal.App.4th 326, 337 ["a duty to disclose may arise from the relationship between seller and buyer, employer and prospective employee, doctor and patient, or parties entering into any kind of contractual agreement. All of these relationships are created by transactions between parties from which a ***duty to disclose facts material to the transaction arises*** under certain circumstances"].) Gilead does not disagree with this established law; indeed, Gilead itself cites *LiMandri* for the exact same proposition. (Pet., 58-59.)

Rather, Gilead's disagreement is based on its contention that as a matter of law the information about TAF could not possibly have been material to the decisions of patients and doctors to take, and continue to take, TDF. However, the Superior Court correctly rejected Gilead's "granular" argument, ruling that the evidence indeed supports a reasonable conclusion that "the TAF medication information that Gilead did not share with prescribing physicians is material." (10App.3252.) The court cites to a wealth of evidence in the record, much of it from Gilead's internal documents and admissions, revealing that Gilead knew this information, including the GS-120-1101 study – would affect HIV treating physician's prescribing habits, because the data revealed that TAF not only had increased anti-HIV activity than TDF, but also had substantially less dangerous side effects than the TDF physicians were prescribing to their patients.[10] Yet Gilead concealed and suppressed this information from patients and their doctors so that the doctors would continue to prescribe, and their patients would continue to take, Gilead's TDF drug, which, among other things, the data showed actually underperformed relative to Gilead's marketing and public perception. (See generally, Real Parties' Additional Factual Allegations, Nos. 20-27, *supra*.; 7App.2155)

Gilead suppressed this material information because Gilead realized sales of TAF would prematurely reduce the sales of TDF, as patients switched from one treatment regimen to another. Gilead was concerned that TAF had the potential to cannibalize its TDF-based drug, Viread, if not positioned strategically. (6App.1922,1944-1945.) Thus, Gilead went to

[10] See 10App.3252 (Superior Court Opn. 16), citing Exhibits in the record, found at 3App1170-1231;5App1662-1670; 5App1702-1724;6App.1910-1931; 6App.1939-1948;7App.2155-2159;7App.2195-2200;7App.2277-2318;7App.2327-2363;7App.2387-2395;7App.2409-2452;8App.2563-2583; 8App.2626 to 9App.2785; 9App.2796-2818;9App.2829-2959.

great lengths to "ensure dissemination of the correct commercial messages" to the public, *i.e.*, to conceal the true reason it was discontinuing TAF development and instead to tell the public that "[TAF] would have continued if Viread did not have such an excellent profile." (7App.2156-2157.)

Gilead went so far as to inform investigators of the GS-120-1101 clinical study — a study comparing TAF and TDF head-to-head — that it would not present nor publish the findings, so as "to avoid generating frustration" in the medical and scientific community. (7App.2195.) Gilead's President even admitted to suppressing the 1101 study because it would "suggest that [TDF] wasn't the safest thing on the market…It didn't seem like the best. It seemed like we would have a mix[ed] message." Gilead thus knew that releasing the clinical study findings too early would cause concern among HIV treaters regarding TDF's supposed safety and impact their decision to prescribe TDF over other FDA- approved drugs (*e.g.*, lamivudine, ritonavir, zidovudine, Epzicom, etc.). (7App.2392-2393.)

Gilead withheld this material TAF data for years and only published the data when disclosure furthered its financial goals. When Gilead restarted TAF development in 2010-2011, it knew it needed to convince healthcare providers to switch to TAF in 2015 and it used the GS-120-1101 clinical study data as part of its efforts to do so. (9App.2829-2959.) Gilead cited to findings from clinical and nonclinical studies – all of which had been completed prior to its 2003 decision to shelve TAF – as "supportive of project continuation." (8App.2565.) It was imperative that TAF and TAF-based coformulations be approved by 2015 so that Gilead could "convinc[e] HIV prescribers to switch as many patients as possible from a TDF-containing regimen to a [TAF]-containing regimen" before 2018 (when TDF generics would hit the market). (Ibid.) Between 2010 and 2012, Gilead executives continuously touted TAF's superior profile to

investors and the general public using the same preclinical and clinical findings available to it when it shelved TAF development in 2004. (8App:2626-9App:2785.) Thus, Gilead's vigorous effort (once it became profitable to do so) to disseminate the very information it concealed for years shows that Gilead clearly understood the information about TAF it had concealed from patients and physicians for years was material to their decision to continue prescribing and using TDF.[11]

The superior court in its ruling cited to all of the foregoing evidence to support its finding that the information that Gilead concealed from patients and their treaters was indeed material to the providers' decision to prescribe and the patients' decision to consume and continue to consume Gilead's TDF drug. (10App.3252.) Thus, based on fundamental legal principles and ample evidence in the record supporting the materiality of the information concealed by Gilead, the superior court properly rejected Gilead's argument that this information that it concealed from the public and particularly physicians treating the patients consuming TDF was not material as a matter of law.

Similarly, Gilead's related assertion that the "transaction" between it and the patients and their doctors must involve the prescription of TAF is unsupported by any legal authority. (Pet. at 59,63; Reply 26.) Gilead concedes there was indeed a transaction related to the prescription of its TDF medication – which is the relevant transaction forming the basis of Plaintiffs' concealment claim. (Id.) And the evidence supports the reasonable finding that Gilead's concealment of the TAF clinical data in

[11] Applying the common and fundamental duty to disclose material facts on drug manufacturers is consistent with the universal concept that there is never a rationale, in any area of medicine, to allow a drug company to conceal or suppress material information that could impact the patient or the prescribing physician from deciding to prescribe or continue to prescribe the company's drug. (7App.2411-2415,2444-2445;9App.2798.)

GS-120-1101, along with that study's negative implications for TDF's performance, materially impacted healthcare providers' prescribing habits as it related to TDF medications. Gilead withheld this information because it feared that disclosure would impact providers' decision to prescribe TDF over other commercially available drugs. It is this transaction – not the prescription of TAF – that is the foundation of Gilead's duty to disclose and that is the basis of Plaintiffs' fraudulent concealment claim.

Gilead has cited no authority contrary to the established law allowing claims for fraud and concealment based on a defendant's duty to disclose facts that are material to the transaction between the parties. Nor has Gilead cited any authority for the proposition that the material information suppressed or concealed must only be about the specific dangers of TDF as opposed to any other material fact – here the superior safety of TAF - that would have influenced Plaintiffs' and their medical providers' decision to act.[12]

For these reasons, the superior court's ruling denying summary adjudication of real parties' claim for fraud and concealment should not be disturbed.

[12] None of the cases Gilead cites discusses, much less holds, that in order to be material the information suppressed or concealed must be about the specific product consumed. As the superior court found below, Gilead is essentially attempting an end-run around the established law on fraudulent concealment which simply requires only that the information concealed would have materially affected the consumer's decision to consume the defendant's product. Here, as the evidence reveals, Gilead knew that releasing its clinical study findings too early would cause concern among HIV treaters regarding TDF's supposed safety and impact their decision to prescribe TDF over other FDA- approved drugs. The element of materiality clearly exists and precludes summary adjudication of real parties' fraud and concealment claim.

IV.

CONCLUSION

For the foregoing reasons Defendant's Petition should be denied in its entirety.

Dated: September 19, 2022

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CERTIFICATE OF WORD COUNT

This brief contains 13,947 words per a computer generated word count.

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PROOF OF SERVICE

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 234 East Colorado Boulevard, Suite 975, Pasadena, CA 91101.

On the date set forth below, I served the foregoing document(s) described as follows: **REAL PARTIES IN INTEREST'S RETURN TO PETITION FOR PEREMPTORY WRIT OF MANDATE, PROHIBITION, OR OTHER APPROPRIATE RELIEF**, on the interested parties in this action by placing ___ the original/ X a true copy thereof enclosed in a sealed envelope(s) addressed as follows:

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☒ STATE I declare under penalty of perjury that the foregoing is true and correct.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this declaration was executed on September 19, 2022 at Honolulu, Hawaii.

s/ Kelsey Wong
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