SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF _ _____

	CASE NO. _____
JOHN DOE 1, JOHN DOE 2 and JOHN DOE 3, Plaintiffs, v. GILEAD SCIENCES, INC., ABC CORPORATIONS 1-100 and JOHN DOES 1-100, Defendants.	**COMPLAINT FOR DAMAGES** **1. NEGLIGENCE** **2. STRICT PRODUCT LIABILITY** **3. BREACH OF EXPRESS WARRANTIES** **4. BREACH OF IMPLIED WARRANTIES** **5. FRAUD AND CONCEALMENT** **DEMAND FOR JURY TRIAL**

COME NOW Plaintiffs, John Doe 1, John Doe 2, John Doe 3, who bring this action against Defendant Gilead Sciences, Inc. ("Gilead") for personal injuries suffered as a result of Plaintiffs' ingestion of the prescription drugs Viread®, Truvada®, Atripla®, Complera® and Stribild® (collectively "TDF-based medications"), all of which are designed, manufactured, marketed, labeled, tested, distributed and/or sold by Gilead for, *inter alia*, the prevention or treatment of Human Immunodeficiency Virus-1 ("HIV"). Plaintiffs' allegations as to their own circumstances are based on their personal knowledge, information or belief. Plaintiffs' allegations as to all other matters are based upon their information and belief after reasonable investigation.

INTRODUCTION

1. This is a straightforward case of a corporation's greed, involving the decision of a pharmaceutical company to withhold for more than a decade, a prodrug for the treatment of HIV that it knew was safer and more effective than the prodrug it had already put into the market.

2. Gilead Sciences, Inc. is a California pharmaceutical giant. Gilead acquired the rights to a drug called tenofovir in the mid-1990s, and secured the exclusive license to synthesize any

tenofovir based compound. Beginning in 2001, Gilead manufactured and sold a prodrug form of tenofovir called TDF. All the while, it had developed another prodrug form of tenofovir called TAF, which it knew to be less toxic to kidneys and bones. Data submitted in 2000 by the company in a patent application – before TDF was even FDA approved -- revealed that Gilead knew TAF was substantially less toxic than TDF. Yet, Gilead shelved the TAF project in 2004 to maximize profits on the existing TDF patent. Gilead entered a market space to the exclusion of all others, leaving its patients with no choice in an already-desperate situation. Under these circumstances, it owed them the safest possible drug. Ten years later in 2014, as the TDF patent came close to an end, Gilead strategically applied for FDA approval for TAF and, in November 2015, brought it to market for the first time.

3. When Gilead introduced TAF to physicians in 2015, it touted the drug as a "new" and "novel" prodrug formulation that was much safer for patients. There was nothing new about it, however. It was the same drug that it kept on the shelf in development since at least 2000. As a result, hundreds of thousands of HIV-infected patients and patients taking the drug prophylactically were exposed to a more toxic form of the drug for over a decade. These patients, including Plaintiffs, unwittingly and needlessly suffered permanent, debilitating, and sometimes fatal kidney and bone damage.

FACTUAL ALLEGATIONS

4. Plaintiffs are each medical patients who were prescribed Gilead's tenofovir and tenofovir-based antiviral medications, namely Viread®, Truvada®, Atripla®, Complera® and/or Stribild®. Plaintiffs were prescribed and ingested these tenofovir-based medications as part of either a "highly active antiretroviral therapy" (HAART) or in combination with other safe sex practices as pre-exposure prophylaxis (PrEP) to reduce the risk of sexually transmitted HIV-1.

5. Antiretroviral medications generally work to prevent the HIV-1 virus from replicating within the body thus reducing the rate of transmission and benefitting an infected person's immune system.

6. Tenofovir is a nucleotide reverse transcriptase inhibitor (NRIT), one of the classes of antiretroviral medications used to prevent and/or treat HIV-1 by blocking an enzyme needed in the viral replication process.

7. In turn, “tenofovir disoproxil fumarate" (TDF) is a “prodrug” of tenofovir, meaning that it is a formulation of tenofovir that is not converted into its active form until it is absorbed into the body.

8. Viread®, Truvada®, Atripla®, Complera® and Stribild® all contain 300 milligrams of TDF, which is the minimum efficacious dose of TDF for the prevention and/or treatment of HIV-1.[1]

9. At all relevant times, Plaintiffs who were infected with HIV-1 ingested some or all these TDF-based medications daily, trusting that they would promote their health by slowing the virus’ replication in their bodies.

10. At all relevant times, Plaintiffs who were not infected with HIV-1 ingested TDF-based medications[2] daily to promote their health as a pre-exposure prophylactic (PrEP) measure in preventing the virus’ transmission.

11. Although Plaintiffs and/or their respective medical providers reasonably expected that these TDF-based medications would promote their overall health by preventing and/or treating the HIV-1 virus, they actually resulted in undisclosed, unanticipated and unnecessary injuries to their kidneys, bones and/or teeth, risks for which an adequate warning was not provided.

12. Gilead’s TDF drugs were developed from 1990-2012. Throughout its development of these TDF drugs, Gilead knew that tenofovir in the prodrug form of TDF was extremely toxic to patients’ kidneys, bones and teeth.

13. At the same time as it developed TDF, Gilead had investigated, discovered, researched and developed a safer, more effective tenofovir “prodrug” called “tenofovir alafenamide

[1] With the exception of Viread®, all of these medications combine TDF with other compounds.

[2] Only Truvada for PrEP® is indicated for pre-exposure prophylactic use.

fumarate" (TAF) that reduced human toxicity and the risk of resulting injury to the kidneys, bones, and/or teeth as compared to TDF.

14. However, despite already having developed a safer form of tenofovir Gilead intentionally, knowingly, willfully, recklessly and/or carelessly marketed first TDF-based medication, Viread® and withheld the safer TAF-based formulations from the market until November 2015, resulting in injuries to the Plaintiffs alleged, *infra*. In so doing, Gilead was able to maximize its profits and fully exploit its own patents on its TDF-based medications.

FACTUAL BACKGROUND

The Early Cultural and Scientific History of HIV-1

15. The HIV/AIDS community has been neglected, marginalized, stigmatized, and discriminated against ever since the disease first entered the public lexicon in 1981 when it was interchangeably referred to as "Gay-Related Immune Deficiency" (GRID), "Gay Men's Pneumonia" and "Gay Cancer".

16. For example, even though the Centers for Disease Control (CDC) estimated in 1982 that tens of thousands of people were already affected by the disease, and anywhere between 854 and 2,304 deaths were attributable to AIDS between 1982-1983, initial efforts to allocate funding for AIDS research were mocked at the highest levels of government with then Press Secretary Larry Speaks going so far as to call the epidemic the "Gay Plague" during a press briefing.

17. It was not until 1984 that the U.S. Department of Health and Human Services announced that researchers at the National Cancer Institute had found the cause of AIDS – a retrovirus they initially labeled HTLV-III before later being renamed HIV-1.

18. During this time, the CDC estimated that 50,280 people were infected with HIV/AIDS, of which 47,993, or 95.5%, died of complications related to the disease, prompting a segment of the general public to support the quarantining of infected people, and the U.S. government to ban travel and immigration by members of the HIV/AIDS community.

19. The pharmaceutical industry's neglect of the HIV/AIDS community came to a head in October 1988, when over 1,000 members and supporters of the activist group ACT UP engaged

in massive sit-ins that shut down the FDA's offices to protest the slow pace of new HIV/AIDS drugs being brought to market.

20. In 1989, members and allies of the HIV/AIDS community railed against the overall lack of treatment options and the astronomical prices of the few available medications, culminating in a series of FDA reforms aimed at expanding clinical trials and increasing access to therapeutic treatments.

21. It was amidst this tumult of ostracization and fear in the HIV/AIDS community that Gilead first assumed its investigation and development of "prodrug" forms through which tenofovir could be offered as an alternative course of treatment for the virus, ultimately resulting in Gilead's securing the exclusive license to synthesize tenofovir-based compounds.

Gilead's Exclusive Development of Tenofovir

22. Tenofovir was first synthesized in 1983 by Antonin Holy at the Institute of Organic Chemistry and Biochemistry of the Academy of Sciences of the Czech Republic in Prague.

23. Initially, Dr. Holy believed that tenofovir was useful in the treatment of Hepatitis B because of its propensity to inhibit the enzymes involved in the disease's replication.

24. These same enzyme-inhibiting properties, in turn, led Dr. Holy to consider whether tenofovir could be useful in the treatment of other viral diseases.

25. In 1985, Dr. Holy contacted long-time associate and collaborator Dr. Erik De Clercq, an immunologist from the University of Leuven in Belgium, to further research the interaction between tenofovir and other viruses.

26. In response to his initial experiments, Dr. De Clercq concluded that tenofovir exhibited remarkable antiviral activity against DNA and RNA viruses, including HIV-1.

27. Although they concluded early on that the compound could not be effectively administered by mouth, Drs. Holy and De Clercq's initial experiments with tenofovir were promising for the treatment of HIV-I and attracted the attention of American pharmaceutical giant Bristol-Myers (now Bristol-Myers Squibb).

28. Recognizing that they needed the financial support to fund additional research and pre-clinical trials, Drs. Holy and De Clercq called upon their ongoing collaborations with Dr. John

C. Martin, the Associate Director of the Anti-Infective Chemistry Department at Bristol-Myers, in 1987, to further study tenofovir's antiretroviral properties.

29. Between 1987 and 1990, Drs. Holy and Martin worked together to synthesize tenofovir compounds for testing by Dr. De Clerq to identify which compounds should be further developed to specifically combat certain diseases.

30. Upon his departure from Bristol-Myers in 1990, Dr. Martin continued his collaborations with Drs. Holy and De Clercq by brokering an exclusive license to research and develop tenofovir-based compounds for his new employer, Gilead.

31. Beginning in 1991, Gilead, under the direction of Dr. Martin as its Vice President of Research and Development, commenced the development of tenofovir as an antiretroviral treatment for HIV/AIDS, focusing first on the identification and design of a viable delivery mechanism.

32. In working to identify and design a viable delivery mechanism for tenofovir, Gilead first considered whether it could develop and market an intravenous formulation, but ultimately scrapped the concept when initial testing revealed that intravenous administration of tenofovir caused a rapid and severe decline in kidney function.

33. As a result, Gilead moved to consider oral formulations of tenofovir, ultimately synthesizing TDF and TAF simultaneously in 1993, and, by 1998, it had concluded initial pre-clinical studies and animal testing that revealed their relative potency, efficacy and cytotoxicity.

34. With respect to TDF, Gilead learned that although the human body converts the compound into tenofovir following oral ingestion, the amount of active tenofovir actually absorbed into the bloodstream was disproportionately low compared to the dose of TDF administered.

35. In order to address TDF's low bioavailability – the amount of a drug actually absorbed into the blood – Gilead determined that a 300 milligram dose was the lowest amount of TDF that could be effectively administered to achieve the desired inhibition of HIV-1 replication.

36. Gilead's scientists also determined this minimum effective dose of TDF resulted in abnormally high concentrations of active tenofovir in the kidneys, which inhibit the kidneys' overall ability to function properly and contribute to mineral losses that precede bone and tooth loss.

37. At the same time it reached these conclusions regarding TDF, Gilead also determined that TAF was a more viable prodrug form of tenofovir that could be administered orally to introduce the same amount of active tenofovir into the body at one-tenth (0.1) of the dose of TDF and achieve the same antiretroviral effectiveness as TDF at only one-thousandth (0.001) of the dose.

38. Stated differently, Gilead found that because of the differences in bioavailability between TDF and TAF, patients needed approximately 12 times more TDF (300 milligram dose) than TAF (25 milligram dose) in order to achieve the same therapeutic effect on viral replication.

39. Given the differences in effective dosage between TDF and TAF, Gilead knew that TAF was associated with less toxicity and fewer side effects because the oral administration of TAF resulted in significantly lower concentrations of active tenofovir in the kidneys, which in turn decreased the risk of renal injuries, as well as bone and tooth loss, when compared to TDF.

40. The relative effectiveness and safety of TAF as compared to TDF was known and confirmed by Gilead as late as July 2001 when it published a paper in *The Journal of Nucleosides, Nucleotides and Nucleic Acids* titled "Metabolism of [TAF], A Novel Phenyl Monophosphoramidate Intracellular Prodrug of PMPA in Blood" concluding that "[TAF] had greater clinical efficacy" relative to TDF, and it publicly presented the same findings at the "Ninth Conference on Retroviruses and Opportunistic Infections – New Drugs, New Data Hold Promise for Next Decade of HIV Treatment" in February 2002.

41. This juxtaposition of effectiveness and safety between the two prodrugs was highlighted as part of Gilead's submissions to the U.S. and European patent offices for TAF where Gilead cited research dating back to 1997 showing *TAF*[3] *was two to three times more potent than TDF and could obtain concentrations of tenofovir in target cells that were ten to thirty times higher than those attainable by TDF*.

[3] Upon information and belief, TAF was also referred to as "GS 7340".

Table 1. *In Vitro* Activity and Stability

	HIV-1 Activity	Cytotoxicity	Stability T 1/2 (min)		
	$IC_{50\mu M}$	$CC_{50\mu M}$	Human Plasma	MT-2 Cell Extract	(P/MT-2)
GS 7340	0.005	> 40	90.0	28.3	3.2
TDF	0.05	70	0.41	70.7	0.006
Tenofovir	5	6000	--	--	--

42. Plainly, at all times relevant to the synthetization, development and research of tenofovir's prodrug forms, Gilead knew that TAF was a safer, more effective and overall better drug than TDF.

The Choice to Promote TDF over TAF

43. Armed with significant knowledge of TDF, TAF and the differences between the two, as well as the exclusive rights to tenofovir, Gilead moved from the development and study of these antiretroviral compounds to the monetization of medications that would be prescribed to patients with HIV/AIDS.

44. In order to maximize its profits and stranglehold on tenofovir-based antiretroviral medications, Gilead intentionally, knowingly, willfully, recklessly and/or carelessly devised a marketing scheme whereby it abandoned the immediate approval, manufacture and sale of TAF in favor of the less effective, less safe TDF. Gilead knew that selling its safer TAF compound first, TDF would never be sold. Conversely, by selling TDF based drugs first, Gilead could reap the benefits of those sales and then, later, market its safer TAF compound and effectively monetize both drugs.

45. Thus, as its scientists were publishing their research regarding TAF's superior safety profile, Gilead began the process of bringing the less effective, less safe TDF to market by conducting clinical trials and, in 2001, submitting its first TDF formulation, Viread®, to the FDA for accelerated approval.

46. Gilead's intentional, knowing, willful, reckless and/or careless promotion of the less effective, less safe TDF over TAF allowed Gilead to artificially extend the period during which it

could exclusively manufacture and sell tenofovir-based drugs for use in preventing and/or treating HIV-1 at the expense of the long term safety and health of the patients it undertook an obligation to treat.

47. In betraying the trust and compromising the well-being of its customers, Gilead was unapologetic about this marketing and distribution scheme, promoting TDF as a "miracle drug" in public while knowing full well that it was concealing the existence and availability of the safer, more effective TAF.

48. Gilead furthered this conceit by intentionally, knowingly, willfully, recklessly and/or carelessly characterizing TDF as a "benign", non-toxic treatment for HIV-1 in the face of evidence that TAF was safer and more effective.

Gilead's TDF-Based Medications

49. All told, Gilead monopolized the market for tenofovir-based antiretroviral medications by designing, marketing and selling five different TDF-based medications between 2001 and 2015:

- Viread® (approved October 26, 2001)
- Truvada® **(**approved August 2, 2004**)**
- Atripla® (approved July 12, 2006)
- Complera® (approved August 10, 2011)
- Stribild® (approved August 27, 2012)

50. Throughout this 14-year period, Gilead's TDF-based medications would sell for anywhere between $1,600 to $2,000 for a month's supply, thereby allowing Gilead to profit from the already-marginalized HIV/AIDS community in excess of $36 billion[4] with little to no regard for patient health, safety and overall quality of life.

[4] Between 2004 and 2015, Gilead's estimated profits for Truvada® alone were $36.2 billion.

Viread®

51. Gilead's machinations to promote its less effective, less safe TDF in order to maximize long term market dominance and financial gain was cemented on October 26, 2001, when it obtained FDA approval for Viread®, which at all relevant times consisted only of a 300 milligram dose of TDF in tablet form.

52. Viread® almost immediately began to dominate the market for antiretroviral medication for the treatment of HIV-1 infections, earning Gilead a staggering $225 million over only two months of sales in 2001.

53. After only six full years of market presence, Viread® grew approximately 1,700% to reach total sales of $4 billion in 2008 despite both external and internal competition.

54. However, as sales of Viread® boomed throughout the 2000s, Gilead continued to generate and receive data further corroborating its existing knowledge that TDF was highly nephrotoxic (i.e. toxic to the kidneys) in comparison to TAF, and therefore more likely to cause significant renal, bone and tooth injuries.

55. For example, in addition to its own internal research and conclusions regarding the safety and efficacy of TDF, Gilead was aware of post-market clinical studies and adverse event reports from as early as 2002, unavailable to the general public, documenting TDF's association with severe renal deficiencies and toxicity in patients without any preexisting history of kidney problems, as well as acute decreases in bone mineral density and tooth loss.

56. These studies also provided evidence to Gilead that prescribers should monitor patients closely for early signs of toxicity, kidney failure or bone loss, and that that medical professionals should discontinue treatment as soon as possible to avoid the risk of permanent injury.

57. As these reports about TDF-related injuries began to emerge within the scientific community in 2002, Gilead contemporaneously funded TAF clinical research throughout the country, which continued to confirm that TAF was both more effective and far less toxic to patients' kidneys, bones and teeth.

58. Rather than publicize this research as it received TDF-related adverse event reports, Gilead suppressed publication of the results, and instead continued to claim through their marketing

materials and sales presentations that TDF was a "risk-free" "miracle drug" for the treatment of HIV-1.

59. With Viread® having grown to account for 68% of its total product sales by the end of 2003, Gilead responded to concerns about TDF not by transitioning to the development and marketing of safer and more effective TAF-based medications, but by implementing plans to design new TDF combination drugs to maintain patent exclusivity and prolong Gilead's ability to charge monopoly prices.

60. In fact, Gilead went so far as to falsely claim that TAF was not different enough from TDF to warrant further development and, in October 2004, Dr. Martin announced that the company would abandon TAF in its future plans to design and produce antiretroviral drugs for the treatment of HIV-1.

Truvada®

61. The first, and arguably most financially successful, of Gilead's monopolizing TDF-based "combination" medications was Truvada®, which was approved by the FDA on August 2, 2004.

62. At all relevant times, Truvada® consisted of 300 milligrams of TDF and 200 milligrams of emtricitabine in tablet form.

63. As a combination drug, Gilead designed Truvada® to extend TDF's market footprint by coupling tenofovir with another Gilead-patented protein inhibitor.

64. The combination of TDF and emtricitabine in Truvada® did nothing to offset or counteract the highly toxic levels of tenofovir being introduced into patients' kidneys, nor did Gilead's prescribing information adequately inform patients and their providers regarding the real risks of toxicity and bone and kidney damage caused by TDF.

65. At the time Truvada® was approved and released to market in 2004, Gilead was aware of published case reports demonstrating a link between TDF and lethal renal toxicity in patients with no prior history of kidney disease.

66. Additionally, over 40% of all adverse event reports received by Gilead for its predecessor TDF-based medication, Viread®, were related to renal injuries, suggesting that the actual number of patients suffering TDF-induced kidney complications was likely much higher.[5]

67. These statistics were corroborated during the 2006 Conference on Retroviruses and Opportunistic Infections where CDC investigators presented data obtained from 11,362 HIV-infected patients treated with TDF-based medications, concluding that this prodrug form of tenofovir was associated with mild and moderate renal insufficiency.

68. Although these results and statistics prompted Gilead – at the insistence of its FDA regulators – to modify its label for Viread® to accurately describe the risks of kidney damage experienced by patients taking TDF on at least seven separate occasions between 2002 and 2008, Gilead's prescribing information for Truvada® continued to distort the risks of renal injury and bone loss as primarily a concern for patients with preexisting renal and bone density conditions.

69. This two-pronged approach of rabid promotion and blatant omission allowed Truvada® to generate significant profits as it exploited the HIV/AIDS community by charging each patient approximately $18,456 per year, resulting in roughly $36.2 billion in total profits by 2015, and further incentivizing Gilead to continue systematically developing and marketing TDF over TAF.

70. In July 2012, Gilead would ultimately expand upon the popularity its marketing scheme created for Truvada® in the HIV/AIDS community to exploit a new indication for pre-exposure prophylactic use by those uninfected with the HIV-1 virus who were at a greater risk of contracting the disease, calling the medication Truvada for PrEP® and exponentially increasing its overall profits.

[5] Post-market adverse events are generally underreported, thus suggesting that the actual number of patients experiencing complications is higher than indicated. *See Empirical estimation of under-reporting in the U.S. Food and Drug Administration Adverse Event Reporting System (FAERS)* (May 2017).

Atripla®

71. Hoping to replicate the success of Viread® and Truvada®, Gilead expanded its monopoly on tenofovir-based antiretrovirals in 2006 by releasing another TDF combination drug, Atripla®, which at all relevant times comprised 300 milligrams of TDF, 200 milligrams of emtricitabine and 600 milligrams of efavirenz.

72. Like Truvada®, Atripla's® addition of other Gilead-patented compounds was not intended to address then-existing and continuously growing concerns regarding TDF-induced renal, bone and tooth injuries, but merely extended Gilead's exclusive ability to market TDF as the premier antiretroviral medication on the market.

73. As was the case for Truvada® and Viread® before it, Atripla's® prescribing information contained the same misrepresentations associated with Gilead's prior TDF-based medications, limiting its warnings to patients with a history of bone and kidney problems, and claiming that the effects of TDF on long-term bone health, bone mineral density and fracture risks were unknown.

74. Of course, Gilead's public release and promotion of Atripla® was also accompanied by the receipt of additional internal and external data continuing to demonstrate that TDF's risks of renal and bone injuries were higher than those associated with TAF, including a post-2006 observational study of 497 HIV-infected patients initiating TDF treatment where nearly 20% developed significant renal dysfunction, as well as the publication of multiple articles between 2008-2011continuing to show that TDF caused marked decreases in kidney functions.

75. Undeterred by this data and the multiple, additional requests by the FDA to change the prescribing information accompanying its TDF-based medications to more accurately reflect the risk of injury[6], Gilead continued its established marketing scheme to promote Atripla® in the HIV/AIDS community, resulting in $2.2 billion in sales during fiscal year 2015 alone.

[6] Specifically, in May 2007, June 2008, August 2008, November 2008 and March 2010, the FDA required Gilead to amend its prescriber information for Viread®, Truvada® and Atripla® to strengthen warnings regarding the risk of renal and bone injuries.

Complera®

76. True to form, Gilead continued its pattern of adding ingredients to its existing TDF-based combination medications in order to extend its monopoly on tenofovir in the treatment of HIV-1 when it received approval for and released Complera® in August 2011.

77. At all relevant times, Complera® was composed of 300 milligrams of TDF, 200 milligrams of emtricitabine and 25 milligrams of rilpivirine in tablet form.

78. Shortly after Gilead began marketing and distributing Complera®, researchers at San Francisco's Veterans' Administration Medical Center and the University of California, San Francisco, in April 2012, published an analysis of the medical records of over 10,000 HIV-infected veterans in the national VA Health Care System – the largest provider of HIV care in the United States – finding that *for each year a patient was exposed to TDF, the risk of TDF-induced renal damage and chronic kidney disease increased by approximately 30%.*

79. These results, in conjunction with the cumulative effect of other, similar studies, eventually lead the FDA to confirm in the spring of 2012 that TDF's safety profile was "well characterized in multiple . . . clinical trials" and "notable for TDF-associated renal toxicity related to proximal tube renal tubule dysfunction and bone toxicity related to loss of bone mineral density and evidence of increased bone turnover."

80. Still, Gilead continued its fervent promotion and distribution of its TDF-based medications, reporting $800 million in sales for Complera® alone in 2015, while an ever-increasing number of patients in the HIV/AIDS community began to discover they were suffering from renal complications and bone injuries caused by their treatment with Gilead's TDF-based medications.

Stribild®

81. Marking the first – and last – departure from its pattern of extending its tenofovir monopoly by combining other Gilead-patented compounds with TDF, Gilead released Stribild® after obtaining FDA approval on August 27, 2012.

82. At all relevant times, Stribild® consisted of 300 milligrams of TDF, 200 milligrams of emtricitabine, 150 milligrams of elvitegravir and 150 milligrams of cobicistat in tablet form.

83. Unlike its predecessor TDF-based medications, Gilead designed Stribild® to include cobicistat, a pharmacoenhancer or "booster" that inhibits the breakdown of elvitegravir, allowing it to remain in the human body long enough to permit effective, once-daily dosing.

84. Just as it knew years before releasing its first antiretroviral medications that TDF generally increased the risk of renal injury and bone loss, Gilead was aware as early as 2006 that tenofovir concentrations in patients' blood increased significantly when taken in conjunction with a booster and that TDF-associated renal toxicity occurs more frequently in patients taking TDF as part of a boosted regimen.

85. Despite its knowledge of these risks, Gilead initially declined to include specific evidence in its marketing and prescribing information drawing patient and provider attention to the use of a booster like cobicistat relative to the increased the likelihood of significant, TDF-induced renal and bone complications.

86. As a result, Gilead knew before and during its promotion and distribution of the medication that Stribild® would be its most nephrotoxic formulation of TDF-based medication, significantly elevating the risk of kidney and bone damage to unsuspecting patients, yet it embraced the opportunity to once again exploit the HIV/AIDS community to the tune of $1.5 billion in 2015.

The Strategic Re-Introduction of TAF

87. By 2015, Gilead's designs to artificially extend its dominance over the market for tenofovir-based antiretroviral medications was drawing to an end as the patent on its first TDF-based medication, Viread®, was set to expire in 2017.

88. Reflecting on the monumental financial success it built via TDF-based medications over the course of 14 years at the expense of the HIV/AIDS community, culminating in a total portfolio of sales of $11 billion in just 2015, Gilead transitioned to implement the current phase of its decades-long plan to continue monopolizing tenofovir into the foreseeable future.

89. For example, even though Gilead had publicly stated up to this point that it had abandoned the development of TAF because of its similar safety profile as compared to TDF, in reality, Gilead worked internally since 2004 to obtain no less than seven separate patents related to the use of TAF in preventing and/or treating HIV-1.

90. These same internal efforts were relayed to investors as early as October 2010 when Gilead's Chief Scientific Officer, Norbert Bischofberger, explained during an earnings call how TAF's safety profile is superior to TDF, particularly with respect to kidney and bone toxicity.

91. During this same earnings call, Dr. Bischofberger went on to describe "[TAF] is a 'prodrug' that delivers more antivirally active components into the compartment in the body where it's really needed . . . What that means is that you can take a lower dose, and actually, our clinical study would indicate one-sixth to one-tenth the [TDF] dose, and you would actually get higher efficacy with less exposure. So we are looking at this to be used in sub-population where people have a concern with [TDF], and the one with renal impairment, elderly people that have reduced renal function, and the other population will be adults that have pre-existing or suspicion of bone disease, osteoporosis, and that's where we are initially going to position the compound."

92. This scheme was shared with Gilead investors again by then President and Chief Operational Officer John Milligan on March 2, 2011, at the Capital Markets Healthcare Conference where he stated that:

> [o]ne of the reasons why [Gilead was] concerned about developing [TAF] was [Gilead was] trying to launch Truvada . . . [a]nd to have [its] own study suggesting that Viread wasn't the safest thing on the market . . . didn't seem like the best . . . There are some concerns still on kidney toxicity and there are some concerns about bone toxicity.

93. Later that same month at the Roth Capital Partners Growth Stock Conference, Mr. Milligan called TAF the "kinder, gentler" version of Viread® because it is safer than TDF, particularly as patients take the medication over extended periods.

94. All told, Gilead stated in 2011 that it recognized promoting TAF is ". . . important because as the age of the AIDS population continues to increase . . . you get issues with aging such as renal function and bone mineral density that can become bigger issues for these patients . . .", defining these "issues" as an "unmet medical need."

95. Shortly thereafter, in January 2012, Gilead began Phase II clinical trials of TAF-based medications and identified a dose that is ten times lower than Viread® while providing greater antiviral efficacy.

96. By October 2012, Gilead concluded these Phase II clinical trials, finding that a once-daily single tablet containing only 10 milligrams of TAF-based medication demonstrated better markers of bone and kidney effects when compared with the 300 milligram dose of TDF found in Stribild®.

97. As Gilead quickly launched into Phase III clinical development, the company's narrative conspicuously transitioned from downplaying the differences between TDF and TAF to proclaiming the latter as a "new" and "better" drug for the treatment of the HIV-1 virus.

98. Not surprisingly, Gilead's characterization of TAF as a "better" option allowing for lower systemic tenofovir exposure, renal toxicity and bone effects without sacrificing efficacy when compared to TDF formed the heart of its application to the FDA for approval of its first TAF-based medication, Genvoya®.

99. More shocking, however, was Gilead's bold reliance on TAF data obtained by the company *before 2005* showing that: (1) TAF provided greater intracellular distribution of tenofovir while yielding lower plasma tenofovir levels than TDF; (2) TAF was less likely to accumulate in the renal proximal tubules, leading to an improved overall safety profile; and (3) TAF doses were far lower than necessary for equivalent TDF-based medications.

100. As a more effective, safer and overall superior antiretroviral medication, the FDA approved Gilead's first TAF-based medication, Genvoya®, on November 5, 2015, ushering in a new era of Gilead's monopolization over the use of tenofovir in the prevention and/or treatment of HIV-1 that would see the introduction of four new, TAF-based medications over the last four years, thereby extending Gilead's market dominance through 2038:

- Genvoya® (approved November 5, 2015)[7]
- Odefsey® (approved March 1, 2016)[8]
- Descovy® (approved April 4, 2016)[9]
- Biktarvy® (approved February 7, 2018)

101. Proving that fate is not without a sense of irony, Gilead's marketing ethos since the approval of its first TAF-based medication in 2015 has focused on extolling the virtues of TAF as "the safest", most effective option for the prevention and/or treatment of the HIV-1 virus, all the while profiting from a history of elevating its bottom line over the health and safety of its most marginalized patients.

THE PARTIES

Gilead Sciences, Inc.

102. Defendant, Gilead Sciences, Inc., is a California resident corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 333 Lakeside Drive, Foster City, California 94404. Gilead is a pharmaceutical company that develops and commercializes prescription medicines from its facilities in California, including Viread®, Truvada®, Atripla®, Complera® and Stribild®, all of which were prescribed for and ingested by Plaintiffs.

[INCLUDE INFORMATION FOR PLAINTIFF]

JURISDICTION AND VENUE

103. This Court has jurisdiction over the subject matter of this action pursuant to California Code of Civil Procedure § 410.10 because a substantial portion of Gilead's acts and Plaintiffs' injuries occurred within California. This court has general and specific personal jurisdiction over Gilead as it is headquartered in California and its acts and/or omissions in the state

[7] Marketed as a direct TAF-based alternative for Stribild®.

[8] Marketed as a direct TAF-based alternative for Complera®

[9] Marketed as a direct TAF-based alternative for Truvada®

of California give rise to the claims at issue in this lawsuit. Specifically, Gilead's decisions to withhold TAF and to aggressively market its unsafe TDF-based drugs all emanated from California.

104. Venue is proper in the County of San Francisco pursuant to California Code of Civil procedure §§ 395 and 395.5 because Gilead conducts business in San Francisco County and a substantial portion of Gilead's acts or omissions at issue in this lawsuit occurred in the County of San Francisco.

TOLLING OF THE STATUTE OF LIMITATIONS

105. Gilead misrepresented that TAF was "new" despite knowing the relative benefits and safety compared to TDF long before Gilead brought any TDF-based drug to market in or about 2001.

106. Gilead misrepresented the reasons that it abandoned the development of TAF in 2004, asserting that TAF could not be differentiated from TDF when it knew that TAF was, in fact, more effective and safer than TDF.

107. For years, Gilead concealed that it abandoned TAF in 2004 in order to extend the lifecycle of its less effective, less safe TDF-based product portfolio despite knowing that patients were experiencing TDF-induced kidney and bone injuries.

108. Gilead concealed the true risk of kidney and bone injuries associated with TDF, as well the need to monitor all patients for TDF-associated toxicity and complications.

109. Neither Plaintiffs nor their medical providers had any reason to suspect that Gilead's wrongdoing was the cause of their injuries and could not have readily discovered their claims.

110. No reasonable person taking TDF-based drugs and experiencing kidney and bone toxicities would have suspected that Gilead purposefully withheld a safer design that would have reduced the likelihood and/or extend of those very side effects.

111. Gilead's intentional, knowing, willful, reckless and/or careless misrepresentations and/or omissions would lead a reasonable person to believe that he or she did not have a claim for relief.

112. Because of Gilead's intentional, knowing, willful, reckless and/or careless misrepresentations and/or omissions, neither Plaintiffs nor any other reasonable person would have

had reason to conduct an investigation; however, once Plaintiffs suspected that Gilead's wrongdoing was the cause of their injuries, they were diligent in trying to uncover the facts and present their claims for relief.

113. Gilead's intentional, knowing, willful, reckless and/or careless misrepresentations and/or omissions regarding its decision to withhold TAF-based products from the market and conceal the true risks of TDF constitute continuing wrongs that exist to this day.

THE CAUSES OF ACTION

COUNT I

NEGLIGENCE

114. Plaintiffs reallege and incorporate by reference each allegation previously set forth in this Complaint for Damages as if the same were stated more particularly at length here.

115. At all times relevant to its design, manufacture, promotion and distribution of antiretroviral medication, Gilead had a duty to exercise reasonable care in the design, manufacture, marketing and sale of its pharmaceutical products, including, but not limited to, its TDF-based medications.

116. In fact, by the manner in which it undertook to exclusively design, manufacture, promote and distribute tenofovir-based antiretroviral medications for the HIV/AIDS community – to the legal exclusion of all others – Gilead voluntary assumed and/or undertook a legal and factual duty to exercise reasonable care, and to comply with the standard of care, in the design, manufacture, marketing and sale of its pharmaceutical products, including, but not limited to, its TDF-based medications.

117. Gilead's duties in these respects included the duty to refrain from selling unreasonably dangerous products, as well as the duty to ensure that its pharmaceutical products do not cause patients to suffer from foreseeable risks of harm.

118. Gilead's duties in these respects also included the duty to monitor the adverse effects associated with its pharmaceutical products, including its TDF-based medications.

119. Gilead had a duty to exercise reasonable care when it undertook affirmative acts for the protection of others, including, but not limited to, the development, promotion and distribution of antiretroviral medications for the prevention and/or treatment of HIV-1.

120. Gilead owed these duties to Plaintiffs because it was foreseeable to Gilead that patients like Plaintiffs would ingest and consequently face increased risks of harm as the result of its TDF-based medications.

121. Gilead knew that the TDF it incorporated into its TDF-based medications was associated with elevated risks of kidney and bone toxicity, and caused injuries that resulted from kidney and bone toxicity, including in patients not otherwise at risk for such injuries.

122. Gilead knew, before marketing its first TDF-based medications, and upon the release of every subsequent TDF-based medication, that TAF is safer than TDF in that it reduces the risks of kidney and bone toxicities, and Gilead was duty bound to act reasonably, in accordance with the standard of care, and in accordance with that knowledge.

123. Despite knowing that TAF would reduce reasonably foreseeable harm to patients' kidneys and bones, Gilead repeatedly incorporated the TDF design into its antiretroviral medications and denied patients the opportunity to take a more effective and safer TAF-based medication, all in order to maximize its financial gain.

124. With thousands of patients experiencing damage to their kidneys and bones as a result of unnecessary TDF exposure – some of which is severe and irreversible – Gilead knew that the likelihood and severity of the kidney and bone injuries suffered by patients like Plaintiffs far outweighed the burden in taking safety measures to reduce or avoid the harm.

125. Gilead failed to use the amount of care in designing its TDF-based medications that a reasonably careful manufacturer would have used to avoid exposing patients to foreseeable risks of harm when taking into account its actual and/or constructive knowledge that TAF was safer and more effective than TDF.

126. Gilead undertook to develop and market safe antiretroviral medications to sell to wholesalers and other direct purchasers of pharmaceuticals, recognizing that its development and marketing of such medications was for the protection of patients like Plaintiffs; however, in

abandoning the safer TAF design purely for monetary gain and misrepresenting why it was abandoning the safer TAF design, Gilead failed to exercise reasonable care in the performance of this undertaking that increased the risk of harm to patients and, in fact, directly and proximately caused the Plaintiffs' injuries.

127. Gilead knew or reasonably should have known that the TDF-based medications were dangerous or likely to be dangerous when used in a reasonably foreseeable manner, especially when compared to the more effective and safer TAF.

128. By designing the TDF-based medications to contain TDF when it knew TDF harmed patients' kidneys and bones at much higher rates than TAF, and intentionally withholding the safer TAF design from the market, Gilead acted in reckless disregard of, or with a lack of substantial concern for, the rights of others.

129. As a direct, proximate and legal result of Gilead's recklessness, carelessness and/or negligence, and in violation of the then existing standards of care, all Plaintiffs were caused to suffer the injuries alleged individually, *supra*.

COUNT II

STRICT PRODUCT LIABILITY

130. Plaintiffs reallege and incorporate by reference each allegation previously set forth in this Complaint for Damages as if the same were stated more particularly at length here.

131. Gilead designed, developed, manufactured, fabricated, tested or failed to test, inspected or failed to inspect, labeled, advertised, promoted, marketed, supplied, and distributed the aforementioned TDF-based medications.

132. Gilead undertook to design these medications with the TDF prodrug formulation so that they could make maximize profits on sales of TDF-based medications even though it was aware that TAF-based medications would provide more efficacy and a better safety profile at a substantially lower dose.

133. Gilead delayed the release of and/or did not release these safer and more effective formulations in order to monopolize the market and maximize profits on sales of TDF and later on sales of TAF.

134. The TDF-based medications manufactured and supplied by Gilead were defective and unsafe for their intended purpose in that the ingestion of these TDF-based medications caused serious injuries and/or death, especially when compared to TAF-based medications.

135. The defects existed in the TDF-based medications at the time they left Gilead's possession.

136. The TDF-based medications did, in fact, cause personal injuries as described above while being used in a reasonably foreseeable manner, thereby rendering them defective, unsafe, and dangerous for use.

137. Gilead placed the TDF-based medications it manufactured and supplied into the stream of commerce in a defective and unreasonably dangerous condition in that these TDF-based medications did not meet the ordinary safety expectations of patients and/or their prescribing physicians.

138. Gilead's TDF-based medications were defective and unreasonably dangerous because their design included TDF and presented excessive dangers that were preventable by designing the drugs to use the TAF prodrug formulation.

139. Gilead knew that TAF was a safer and more effective design for delivering the drug tenofovir to the body and that TAF was capable of reducing the risk of bone and kidney damage to patients.

140. At all times relevant to this matter, Gilead was aware that members of the general public who would ingest their TDF-based medications, including Plaintiffs, had no knowledge or information indicating that use of these medications would increase their risks of suffering the alleged injuries and that a safer alternative existed in TAF.

141. Gilead further knew that members of the general public who used their TDF-based medications, including Plaintiffs, would assume, and in fact did assume, that this use was safe, when in fact it was extremely hazardous to health and human life.

142. Gilead undertook to manufacture, design, label, distribute, offer for sale, supply, sell, package, and advertise the TDF-based medications without attempting to protect said users from, or warn of, the high risk of injury or death resulting from their use.

143. Gilead intentionally failed to reveal their knowledge of the risks, failed to warn of the risks and consciously and actively concealed and suppressed said knowledge from members of the general public, including Plaintiffs, thus impliedly representing to members of the general public that the TDF-based medications were safe for all reasonably foreseeable uses.

144. Gilead was motivated by their own financial interest in the continuing uninterrupted manufacture, supply, sale, marketing, packaging and advertising of tenofovir based medications.

145. Gilead deliberately disregarded the safety of patients and in fact was consciously willing to permit the TDF-based medications to cause injury.

146. Gilead's conduct was and is willful, malicious, fraudulent, outrageous and in conscious disregard of and indifferent to the safety and health of the patients using their TDF-based medications.

147. As a direct, proximate and legal result of the defective and unreasonably dangerous condition of the TDF-based medications Gilead tested, manufactured and supplied, and the lack of adequate use instructions and warnings, Plaintiffs were caused to suffer the injuries and damages described, *supra*.

COUNT III

BREACH OF EXPRESS WARRANTY

148. Plaintiffs reallege and incorporate by reference each allegation previously set forth in this Complaint for Damages as if the same were stated more particularly at length here.

149. The aforementioned manufacturing, compounding, packaging, designing, distributing, testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising, promoting, supplying and selling of the TDF-based medications were expressly warranted to be safe for Plaintiffs' use as well as for other members of the general public.

150. At the time of the making of the express warranties, Gilead knew the purpose for which their TDF-based medications were to be used and warranted their TDF-based medications to be in all respects, fit, safe, and effective and proper for such purpose.

151. The TDF-based medications were unaccompanied by warnings of their dangerous propensities that were known or knowable to Gilead at the time of distribution.

152. In using Gilead's TDF-based medications, Plaintiffs and their physicians reasonably relied on Gilead's skill and judgment and on the express warranty, were untrue in that the TDF-based medications were unsafe and, therefore, unsuited for the uses for which they were intended.

153. The TDF-based medications could and did cause Plaintiffs to suffer and continue to suffer the injuries and damages described, *supra*.

COUNT IV

BREACH OF IMPLIED WARRANTY

154. Plaintiffs reallege and incorporate by reference each allegation previously set forth in this Complaint for Damages as if the same were stated more particularly at length here.

155. At all relevant times, Gilead manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold the TDF-based medications, and prior to the time they were prescribed to Plaintiffs, Gilead impliedly warranted to Plaintiffs, their physicians and healthcare providers, that the TDF-based medications were of merchantable quality and safe for the use for which they were intended.

156. Plaintiffs, their physicians and healthcare providers relied on Gilead's skill and judgment in using the TDF-based medications.

157. The TDF-based medications were unsafe for their intended use and were not of merchantable quality, as warranted by Gilead at law and/or according to statute, including, but not limited to, California, U. Com. Code § 2314, in that they had very dangerous propensities when used as prescribed and intended that would cause severe injuries to the patient.

158. The TDF-based medications were unaccompanied by sufficient warnings of their dangerous propensities that were either known or could reasonably have been ascertained by Gilead at the time of distribution.

159. As a direct, proximate and legal result of the defective and unreasonably dangerous condition of the TDF-based medications manufactured and supplied by Gilead, Plaintiffs were caused to suffer and will continue to suffer the injuries and damages described, *supra.*

160. After Plaintiffs were made aware that their injuries were a result of the TDF-based medications, notice of the breach of warranty was duly provided to Gilead.

COUNT V

FRAUD AND CONCEALMENT

161. Plaintiffs reallege and incorporate by reference each allegation previously set forth in this Complaint for Damages as if the same were stated more particularly at length here.

162. At all relevant times, Gilead had the duty and obligation to truthfully represent the facts concerning its TDF-based medications to Plaintiffs and their healthcare providers pursuant to federal and state law.

163. California Civil Code § 1709 provides that one who willfully deceives another with intent to induce him to alter his position to his injury or risk is liable for any damages which he thereby suffers.

164. California Civil Code § 1710 provides, in part, that a deceit, within the meaning of § 1709, is the suppression of fact, by one who is bound to disclose it, or who gives information of other facts which are likely to mislead for want of communication of that fact.

165. Defendants willfully deceived Plaintiffs, their healthcare providers, the medical community, and the public in general, by concealing material information concerning Gilead's TDF-based medications, which Gilead had a duty to disclose, thus misrepresenting the true nature of the medications.

166. As described *supra*, Gilead concealed material facts concerning the TDF-based medications from Plaintiffs, their physicians, and other healthcare providers.

167. Specifically, Gilead actively concealed:

a. the safer TAF design for delivering tenofovir into the body prior to seeking and receiving FDA approval for the TDF-based medications even though it knew that TDF posed a significant and increased safety risk to patients' kidneys and bones;

b. that the toxicity associated with tenofovir was not unavoidable;

c. the real reason Gilead abandoned its TAF design in 2004, which was not because TAF could not be sufficiently differentiated from TDF;

d. the TAF design, which it knew was safer than TDF, solely to maximize profits; and

e. a warning to doctors to frequently monitor all patients for the adverse effects of TDF toxicity.

168. Gilead knew that this information was not readily available to Plaintiffs and their doctors, and Plaintiffs and their doctors did not have an equal opportunity to discover the truth.

169. Plaintiffs and their doctors had no practicable way of discovering the true state and timing of Gilead's knowledge.

170. Gilead intentionally, willfully and maliciously concealed and/or suppressed material information from prescriber and patient labeling regarding the need for doctors to monitor all TDF patients on a frequent, specific schedule, for the adverse effects of TDF-associated bone and kidney toxicity.

171. Gilead intentionally, willfully and maliciously concealed and/or suppressed an adequate monitoring warning in order to conceal the true risk of its TDF-based medications, and to inflate sales by inducing doctors to prescribe, and patients like Plaintiffs to consume, its TDF-based medications.

172. By providing inadequate warnings that were contrary to those it gave with respect to the exact same drugs in other countries, Gilead intentionally, willfully and maliciously concealed and/or suppressed material facts.

173. Gilead had a duty of complete disclosure once it undertook to speak.

174. Plaintiffs and their doctors justifiably relied on Gilead's product labeling and other representations.

175. Had Gilead not intentionally, willfully and maliciously concealed and/or suppressed this information about the safe use of its TDF-based medications from the prescriber and patient labeling, doctors would have performed, and patients would have insisted upon, frequent and adequate monitoring for the kidney and bone problems that have injured Plaintiffs.

176. If Plaintiffs had been adequately monitored for kidney and bone problems while taking TDF-based medications, they would not have been injured or their injuries would have been less severe.

177. Gilead intentionally, willfully and maliciously concealed and/or suppressed from Plaintiffs and their doctors the fact that Gilead had already developed the safer TAF mechanism but designed the TDF-based medications to contain TDF instead of the safer TAF design in order to maximize profits on its TDF-based medications and extend its ability to profit on its HIV franchise for years to come.

178. Gilead actively concealed these material facts by, inter alia, misrepresenting: (a) that any tenofovir-induced toxicity was rare and unavoidable; (b) why Gilead had purportedly abandoned development of TAF in 2004; and (c) that TAF was "new" once Gilead finally introduced the safer TAF-based medications over a decade later.

179. By concealing that Gilead was aware of but had withheld the safer designs, Gilead intended to and did induce Plaintiffs' doctors to prescribe, and Plaintiffs to ingest, one or more of the TDF-based medications, thereby causing Plaintiffs' injuries.

180. Plaintiffs and their doctors justifiably relied on Gilead's omissions regarding TAF.

181. As a direct, proximate and legal result of Gilead's material omissions, Plaintiffs were caused to suffer and will continue to suffer the injuries and damages described, *supra.*

WHEREFORE, Plaintiffs pray for judgment against Defendant, Gilead Sciences, Inc., and as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiffs, as follows:

a. economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

b. for compensatory damages according to proof;

c. for declaratory judgment that Gilead is liable to Plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by Gilead's wrongdoing;

d. for disgorgement of profits;

e. for an award of attorneys' fees and costs;

f. for prejudgment interest and the costs of suit;

g. punitive or exemplary damages according to proof; and

h. for such other, further and different relief as this Honorable Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all claims in this action.

Respectfully submitted,

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