IN THE CIRCUIT COURT OF THE FIFTEENTH JUDICIAL CIRCUIT IN AND FOR PALM BEACH COUNTY, FLORIDA

PHILIP B. EPSTEIN,

Plaintiff,

v.

GILEAD SCIENCES, INC., CHARLES PACKARD, CESAR PIZARRO, and LUIS GRULLON,

Defendants.

_____/

CASE NO.

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Philip B. Epstein ("Plaintiff" or "Epstein") brings this civil action to recover monetary damages against Defendants Gilead Sciences, Inc. ("Gilead"), Charles Packer, Cesar Pizarro and Luis Grullon for violations of Florida law.

INTRODUCTION

1. This personal injury action arises out of injuries Plaintiff Philip B. Epstein sustained as a result of having ingested the prescription drugs Atripla and Viread which were manufactured and sold by defendant Gilead for the treatment and management of Human Immunodeficiency Virus-1 ("HIV") infection.

2. Atripla and Viread are antiretroviral medications taken as a once per day pill. They contain the drug compound tenofovir which, when activated inside the human body, fights HIV by blocking the protein that HIV needs to replicate itself.

3. Epstein was diagnosed with HIV in the summer of 2007 and was first prescribed

Atripla in July 2007. His physicians switched him to Viread in or about February 2008. He ingested these antiretroviral medications until August 2010 when his physicians changed his antiretroviral regimen to one that did not contain tenofovir.

4. When tenofovir is administered orally in its natural form, very little of it is absorbed into the body. Gilead developed a form of tenofovir known as tenofovir disoproxil fumarate ("TDF") which allows tenofovir to remain inactive at the time it is ingested into the body. After absorption into the patient's bloodstream, tenofovir is converted into its active form.

5. A downside of TDF is that a high dosage of 300 mg of tenofovir is typically required to have the desired therapeutic effect.

6. Unfortunately, and unknown to Epstein or his prescribing medical providers, while Epstein's ingestion of Atripla and Viread over approximately three years may have kept his viral load manageable, it caused significant damage to his kidneys and bones.

7. The high required dosage of TDF subjected Epstein's kidneys and bones to daily overexposure to the extremely potent active form of the drug. Such exposure was not needed or even useful in treating his HIV, but, rather, resulted from the excessive amounts of Atripla and/or Viread that his body could not process. The remaining potent and toxic medication instead ended up in Epstein's bones and kidneys.

8. Before Gilead began selling its first TDF drug in 2001, Gilead knew that TDF posed a safety risk to patients' kidneys and bones. Gilead knew that two of its other antiviral drugs with chemical structures similar to tenofovir had been toxic to patient's kidneys and that early data for TDF showed that it could cause significant kidney and bone damage. Gilead also

knew that the relatively high dose of TDF created a greater risk of toxic effects, and that bone and kidney toxicities were even more likely to be seen with long-term use of TDF for the treatment of HIV.

9. Moreover, Gilead also knew, before it obtained approval to market Viread and its other TDF drugs, that it had discovered and tested a similar form of the drug that could be given in lower doses with reduced toxicity to kidneys and bones. This form of tenofovir known as tenofovir alafenamide fumarate ("TAF") is absorbed into the cells HIV targets much more efficiently than TDF and as a result can be administered at a dramatically reduced dose compared to TDF while still achieving the same or higher concentrations of active tenofovir in the target cells. Because TAF can be administered at a much lower dose than TDF, its use is associated with less toxicity and fewer side effects.

10. But, an improved form of the drug would have undercut Gilead's sales of Viread and, Gilead was counting on Viread's once per day pill form to set it apart from the pack of antiretroviral medications already in the market.

11. Falsely claiming that TAF was not different enough from TDF to continue , Gilead suddenly and unexpectedly shelved its TAF design in 2004. However, Gilead senior representatives admitted to investment analysts that the real reason Gilead abandoned the TAF design was that TAF was far different from TDF. Once Gilead's first TDF product, Viread, was on the market, Gilead did not want to hurt TDF sales by admitting that its TDF-based products are unreasonably and unnecessarily unsafe.

12. Gilead was so desperate to expand Viread sales that it repeatedly misrepresented Viread's safety profile when promoting the drug to doctors—falsely calling it a "miracle drug"

with "no toxicities."

13. In addition, Gilead knew that by withholding the safer TAF design, it could extend the longevity of its HIV drug franchise and reap billions in profit: first, with its TDF medications until their TDF patents expired which would begin by no later than 2018, and second, with the patent exclusivity of its TAF medications until as late as 2032. Only once Gilead realized billions in sales through most of the TDF patent life did it seek to market safer TAF- based versions of its HIV medications.

14. Finally, in 2015, Gilead began selling the first of its TAF-designed medicines and convinced doctors to switch their patients from TDF-based to TAF-based regimens by demonstrating TAF's superior safety profile over TDF with respect to kidney and bone toxicity —the very benefits that Gilead could have and should have incorporated into its prior product designs but withheld from doctors and patients for over a decade.

15. In addition to withholding safer designs, Gilead failed to adequately warn physicians and patients about the risks and safe use of TDF. Gilead provided only the weakest, inadequate warnings to doctors and patients about the need for frequent monitoring of all patients for TDF- associated kidney and bone damage—preventing doctors from detecting early signs of TDF toxicity.

16. Gilead provides stronger monitoring warnings to physicians and patients in the European Union ("EU") than it does in the United States for the exact same TDF products. Contrary to its U.S. labeling, Gilead has consistently recommended, since the approval of its first TDF Drug in the EU, that doctors in the EU monitor all TDF Drug patients for multiple markers of TDF toxicity on a frequent, specified schedule. There is no scientific or medical

rationale for these differences. Gilead was more concerned with increasing or maintaining crucial U.S. sales than it was in safeguarding patients from the known risks of TDF.

17. Gilead intentionally withheld a safer alternative design of TDF Drugs it knew to be dangerously toxic to patients' kidneys and bones, while failing to adequately warn about the risks and safer use of the defective drugs, solely to make more money. Accordingly, Plaintiff brings this action to recover damages for his personal injuries and seeks punitive damages arising from Gilead's willful and wanton conduct.

18. Had Epstein's doctors known that Atripla and/or Viread presented a risk of chronic kidney disease for patients without any history of it, they could have chosen another antiretroviral regimen in 2007, switched Epstein's medication along the way, or monitored his kidney function more closely. Antiretroviral

19. As Gilead withheld its safer design and continued to profit from Viread, the years of ingesting Viread and Atripla at the required high doses took their toll on Epstein. He was diagnosed with renal failure and acute kidney injury. He also suffers from neuropathy and bone density loss which has reduced his enjoyment and permanently altered his way of life.

20. Had Gilead not omitted or hidden information about its safer design, Epstein and countless other HIV-infected individuals could have been spared years, if not decades, of unnecessary kidney toxicity.

21. Had Gilead adequately warned Epstein or his providers about the risk of chronic kidney disease and bone toxicity, Epstein and his medical providers could have prescribed one of the other antiviral medications available at that time.

22. Epstein's kidney and bone damage are a direct and proximate result of Gilead's

wrongful conduct in designing, developing, manufacturing, testing, distributing, labeling, advertising, marketing, promoting, and selling the unsafe prescription antiviral drugs, Viread and Atripla.

JURISDICTION, PARTIES AND VENUE

23. Plaintiff brings this action to recover damages in excess of $15,000, exclusive of interest and costs, for medical and other expenses and all general and special damages related to his development of kidney and bone damage and other associated injuries, and for general and specific future damages, and such other relief as requested herein for injuries suffered as a direct result of Epstein's ingestion of Viread and Atripla. At all times pertinent, Epstein used Viread and Atripla in a manner and dosage recommended by Gilead and prescribed by his doctor.

24. Plaintiff Epstein is and was at all relevant times a resident domiciled in Palm Beach County, Florida. Following Plaintiff's diagnosis of HIV in June 2007, Plaintiff was initially prescribed several antiretorival drugs, including Atripla, by his physicians and medical providers in Palm Beach County which he ingested for several months. When it was discovered that Epstein had a resistance to one of the drug components in Atripla, his physicians prescribed Viread which Epstein continued to take for more than two and a half years in combination with other antiviral drugs. Plaintiff purchased these drugs, at the recommendation of his physicians, because Gilead, through its sales representatives, touted its TDF Drugs as risk-free, miracle drugs.

25. Epstein's ingestion of the defective TDF Drugs in Palm Beach County caused him to suffer kidney damage, neuropathy, and bone density loss. Epstein also experienced

Fanconi syndrome which is caused when damage to the kidneys prevents the reabsorption of beneficial compounds in the body leading to osteomalacia (bone disease) and muscle weakness. Plaintiff required and incurred and will continue to require and incur expenses in connection with medical treatment as a result of these injuries. Epstein has endured and will continue to endure pain, suffering, mental anguish, and loss of enjoyment of life as a result of his injuries, and other injuries and damages to be proven at trial.

26. Defendant Gilead Sciences, Inc. is a 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 also maintains an office in Miami-Dade County located at 5200 Blue Lagoon Drive, Suite 450, Miami, Florida 33126. Gilead is a pharmaceutical company that develops and commercializes prescription medicines, including Atripla and Viread, which were prescribed for and ingested by Plaintiff.

27. Defendant Gilead regularly conducts business within the State of Florida and derives substantial revenues from drugs consumed in Florida. At all times relevant to this complaint, Gilead was engaged in the business of manufacturing, promoting, marketing, distributing, and selling pharmaceutical drugs, including Atripla and Viread, throughout the State of Florida and within the County of Palm Beach through its sales representatives and agents.

28. Defendant Charles Packard ("Packard") is *sui juris* and a resident of Jacksonville, Florida. From February 2003 through July 2009, Packard was employed by Gilead as a Regional Sales Director for the Southeast United States and the Caribbean. Upon information and belief, Packard was responsible for a team of sales representatives in Florida

and other states who sold, marketed and promoted Gilead's HIV TDF Drugs to physicians, hospitals and community health agencies in South Florida, including physicians and hospitals. Upon information and belief, Packard helped launch Truvada and Atripla in Florida and he worked to execute a business plan to establish Gilead as the number one pharmaceutical company in the HIV market.

29. Defendant Cesar Pizzaro ("Pizarro") is *sui juris* and a resident of south Florida. Pizarro is a present employee of Gilead and from December 2006 through January 2015, he was responsible for the business and scientific relationship with area physicians, hospitals and community health agencies in South Florida, including upon information and belief Plaintiff's physicians and hospitals, focusing on the promotion of Atripla, Truvada, Complera and Stribild for the treatment of HIV.

30. Defendant Luis Grullon ("Grullon") is *sui juris* and a resident of south Florida. From September 2007 through May 2014, Grullon was employed by Gilead as a Therapeutic Speciality Representative responsible for multiple product launches and the sale of Gilead's anti-retroviral portfolio (*i.e.*, Atripla, Truvada, Stribild and Complera) to physicians, hospitals and community health agencies in South Florida, including upon information and belief Plaintiff's physicians and hospitals.

31. Venue is proper in Palm Beach County because the causes of action herein arose in Palm Beach County and because at all times material Defendants were doing business in and had agents or other representatives working in Palm Beach County.

32. All other conditions precedent have been satisfied or waived.

FACTUAL ALLEGATIONS

A. Use of Tenofovir to Treat HIV

33. Plaintiff Philip Epstein was prescribed and ingested Defendant Gilead's antiretroviral medications, Atripla and Viread, for more than three (3) years in combination with other anti-HIV drugs, a practice known as "combination antiretroviral therapy" or "cART." By using a combination of different classes of medications, physicians can customize treatment based on factors including how much virus is in the patient's blood, the particular strain of the virus, and disease symptoms. The aim of cART is to reduce the viral load, *i.e.*, the amount of virus per unit of blood or plasma, of patients to levels where the presence of the virus cannot be detected.

34. HIV is a retrovirus. A retrovirus cannot replicate on its own, meaning that it has to invade a host cell to complete its life cycle. A retrovirus inserts its genetic material into the target cell it is infecting through a process known as "reverse transcription."

35. Tenofovir is a type of drug which prevents reverse transcription and thereby prevents the infection of the human cell and the spread of HIV.

B. Development and FDA approval of Gilead's TDF Drugs

36. Gilead did not discover or invent tenofovir. Tenofovir was initially synthesized in the mid-1980 and its therapeutic benefits were discovered as a result of the collaborative research efforts of Antonin Holy at the Institute of Organic Chemistry and Biochemistry, Academy of Sciences of the Czech Republic in Prague and Dr. Erik De Clerq, a medical doctor and researcher at the Rega Institute for Medical Research in Belgium.

37. Dr. De Clerq often travelled to visit and conduct research at Bristol-Myers Squibb in Connecticut. His host at Bristol-Myers Squibb, John C. Martin, PhD, would eventually become the head of Gilead's Research and Development in 1990s and one day Gilead's president.

38. Focusing on how to combine HIV medications into fewer pills taken less frequently throughout the day, de Clerq, Martin, and Gilead located tenofovir amongst the thousands of compounds they had licensed from Czech researchers.

39. Gilead purchased the right to sell tenofovir in 1997.

40. Although the anti-HIV properties of tenofovir were promising, it had a significant downside in that it had to be administered intravenously. To be able to market and sell tenofovir as convenient treatment regimen, Gilead developed a "prodrug" form of tenofovir that can be taken orally in a once a day pill. "Prodrugs" are pharmacologically inactive compounds that can be more efficiently absorbed into the bloodstream and then converted into the activated form of the drug within the body.

41. One prodrug of tenofovir is tenofovir disoproxil. The salt form of tenofovir disoproxil, which allows the drug to be more easily dissolved into the body is "tenofovir disoproxil fumarate" commonly known as TDF.

42. While TDF is able to be taken by mouth, the proportion of tenofovir that enters the cells is relatively low. In order to have the desired therapeutic effect, a high dose of TDF (300 mg) must be administered.

43. Between 2001 and 2012 Gilead received FDA approval for five TDF-based drugs for the treatment of HIV: Viread, Truvada, Atripla, Complera and Stribald (collectively,

"TDF Drugs"). Viread contains 300 mg of only TDF while the others contain combinations of 300 mg of TDF and other antiretroviral agents. Specifically,

A. on October 26, 2001, the FDA approved Gilead's new drug application ("NDA") for Viread for the treatment of HIV.

B. on August 2, 2004, the FDA approved Gilead's NDA for Truvada tablets, which is a combination product containing 300 mg TDF and 200 mg emtricitabine, for the treatment of HIV. Neither of the active ingredients in Truvada was new. The FDA approved the Truvada application based primarily on data showing the fixed-dose combination drug was bioequivalent to its separate components.

C. on July 12, 2006, the FDA approved Gilead's NDA for Atripla tablets, which is a combination product containing 300 mg TDF, 200 mg emtricitabine, and 600 mg efavirenz, for use alone as a complete regimen or in combination with other retroviral agents for the treatment of HIV. Gilead submitted no clinical data in support of its NDA. None of the active ingredients in Atripla were new. Approval was based on a demonstration of bioequivalence between the individual components and the fixed-dose combination.

D. on August 10, 2011, the FDA approved Gilead's NDA for Complera tablets, which is a fixed dose combination product containing 300 mg TDF, 200 mg emtricitabine, and 25 mg rilpivirine, for use as a complete regimen for the treatment of HIV in adults who had not been previously

treated for HIV. None of the active ingredients in Complera were new. Gilead submitted no new clinical safety or efficacy trials in connection with its NDA. Approval was based on the results of bioequivalence studies comparing the combination product to the individual component drugs.

E. on August 27, 2012, the FDA approved Gilead's NDA for Stribild, which is a fixed dose combination product containing 300 mg TDF, 200 mg emtricitabine, 150 mg elvitegravir, and 150 mg cobicistat, for use as a complete regimen for the treatment for HIV.

C. Gilead's Development of TAF

44. Before the FDA approved Viread in 2001, Gilead had already discovered another prodrug version of tenofovir originally called GS-7340 but which is now known as tenofovir alafenamide fumarate ("TAF").

45. TDF and TAF are two prodrug versions of the same parent drug, tenofovir, though TAF requires a dose more than ten times smaller than TDF to achieve the same therapeutic effect with fewer side effects.

46. TAF differs from TDF in its penetration into target cells, *i.e.*, cells that HIV infects or "targets." Unlike TDF, which is converted into tenofovir in the gastrointestinal tract, liver, and blood, TAF is not converted into tenofovir until it has been absorbed by the target cell. This allows TAF to be more efficiently absorbed compared to TDF. This more efficient absorption allows TAF to achieve far greater concentrations of tenofovir inside the target cells than even a much larger dose of TDF.

47. The lowered concentrations of tenofovir found with TAF results in reduced toxicity compared to TDF, making TAF safer to use than TDF.

48. By July 2000, more than a year before Viread obtained FDA approval, Gilead submitted provisional patent applications to the U.S. and European patent offices describing TAF, its enhanced uptake by target cells, reduced cytotoxicity, and superior stability and concentration compared to TDF. The provisional patent applications cited Gilead research dating back to 1997 showing TAF was 2-3 times more potent than Viread and that it could obtain concentrations of tenofovir in target cells that were ten to thirty times higher than those attainable with Viread.

49. Gilead also demonstrated that dosing with TAF resulted in dramatically higher concentrations of the drug in all organs except the kidneys and the liver, compared with TDF. This suggested that TAF is uniquely able to target cells that HIV infects, while not concentrating in the kidney.

50. As TDF entered clinical trials, Gilead's scientists published research on TAF's superior profile:

B. TAF "demonstrated good bioavailability" and rapid and efficient conversion into the active drug resulting in high concentrations of tenofovir in target cells.

C. Because TDF "is highly susceptible to hepatic and blood esterases which limits its persistence in plasma and ability to interact directly with target cells," researchers "sought to overcome this limitation with the development of a prodrug [TAF] which is stable in blood."

D. Levels of tenofovir in target cells after "incubation with [TAF] were about 10-fold and 30-fold greater than those after incubation with [TDF]."

E. "[H]igh intracellular levels of [tenofovir] should be an important indicator of greater clinical efficacy of [TAF]."

51. Gilead's research also showed that the TAF design was so efficient at delivering tenofovir to the body, it was virtually undetectable as TAF after it had been metabolized. By contrast, TDF in its prodrug form remained detectable in plasma, a marker of potential toxic exposure to non-target cells and sites. TAF's greater efficiency would require much lower doses of it to be effective.

52. In a 2001 paper, Gilead scientists described the remarkable results achieved when studying the metabolism of TAF in blood. What Gilead found was that one needed only one thousandth (1/1000) of the dose of TAF compared to TDF to achieve the same level of inhibition of HIV replication and only one tenth (1/10) the dose of TAF compared to TDF to reach the same levels of active tenofovir inside cells.

53. Gilead researchers presented the results of its study at a February 2002 conference on retroviruses. Gilead's senior executives stated that its goal with TAF was to deliver a more potent version of tenofovir that can be taken in lower doses, resulting in better antiviral activity and fewer side effects.

54. Gilead's 2001 10-K highlighted the benefits of TAF over Viread: "Both [TAF] and Viread are processed in the body to yield the same active chemical, tenofovir, within cells. However, the chemical composition of [TAF] may allow it to cross cell membranes more easily

than Viread, so that with [TAF], tenofovir may be present at much higher levels within cells. As a result, [TAF] may have greater potency than Viread and may inhibit low-level HIV replication in cells that are otherwise difficult to reach with reverse transcriptase inhibitors."

55. In 2002 Gilead told investors that it had initiated Phase I/II testing of its TAF compound and that it intended to prove that TAF was more potent than Viread, meaning that it could be administered at a safer, lower dose.

56. Likewise in 2003 and 2004, Gilead repeatedly referred to the positive results from clinical studies of its TAF compound.

57. In spite of the clear and growing need to mitigate the risks associated with TDF, Gilead's CEO John C. Martin abruptly announced on October 21, 2004, shortly after the FDA approved the TDF Drug Truvada, that Gilead would abandon its TAF design, stating:

> [W]e have witnessed the increasing use of Viread across all HIV patient populations, and we have also received approval for and launched Truvada. Based on our *internal business review* and ongoing review of the scientific data for [TAF], we came to the conclusion that it would be unlikely that [TAF] would emerge as a product that could be highly differentiated from Viread.

58. Despite Gilead's misrepresentation that TAF could not be "highly differentiated" from Viread and thus was not worth pursuing, Gilead scientists continued to tout the benefits of TAF in May 2005 noting that with TAF it should be possible to reduce the total dose of tenofovir and thereby reduce suboptimal drug exposure during cART.

59. Although Gilead withdrew TAF from clinical development, it continued its financial development of the compound and between October 2004 and May 2005, Gilead secured its interest in the superior prodrug and applied for seven patents associated with TAF.

60. Despite recognizing the safety benefits of TAF, Gilead kept its TAF design on the shelf for years—knowingly exposing patients taking its TDF-containing drug products to greater risks of kidney and bone toxicity.

61. It was not until approximately October 2010—six years after Gilead shelved its safer tenofovir prodrug and after Gilead designed combination products Truvada and Atripla to contain TDF rather than safer TAF—that Gilead renewed development of the safer TAF design.

62. On March 2, 2011, Gilead revealed to investors the real reason Gilead previously refused to design its products to contain the safer TAF design—it did not want to hurt TDF sales by stepping on its TDF marketing message:

> One of the reasons why we were concerned about developing [TAF] was we were trying to launch Truvada versus Epzicom at that time. And to have our own study suggesting that Viread wasn't the safest thing on the market, which it certainly was at the time. . . . It didn't seem like the best. It seemed like we would have a mix[ed] message. And in fact that Viread story is split out to be a fairly safe product over the years. There are some concerns still on kidney toxicity and there are some concerns about bone toxicity.

D. Gilead Knew Before Viread Was Approved That TDF Posed a Significant Safety Risk.

63. Before Gilead's first TDF product, Viread, received FDA approval in 2001, Gilead knew that two of its other antiviral drugs that are structurally similar to tenofovir caused significant kidney damage.

64. Tenofovir is a member of a class of molecules known as "acyclic nucleoside phosphonates." Two of Gilead's other antiviral drugs—cidofovir and adefovir—are also acyclic nucleoside phosphonates. Tenofovir has a nearly identical structure to adefovir, varying only by the presence of a methyl group (*i.e.*, a carbon atom bound to three hydrogen atoms) in

tenofovir, which replaces a hydrogen atom in adefovir.

65. Cidofovir injection, marketed as Vistide, was Gilead's first commercial product. When the FDA approved Vistide in 1996, it carried a black box warning stating that renal impairment is the drug's major toxicity and renal failure resulting in dialysis or contributing to death have occurred with as few as one or two doses of Vistide.

66. The development of Gilead's other antiviral prodrug adefovir was abandoned in December 1999 after it proved too toxic to patients' kidneys in the later stages of Phase III clinical trials. Based on this experience, Gilead knew that adefovir was associated with delayed nephrotoxicity—meaning that its toxic effects might not be felt for some time after continued use.

67. Gilead even recognized in its 10-K for the year ending December 31, 2000, that due to its experiences with nephrotoxicity in Phase III clinical trials of adefovir, delayed toxicity issues similar to those experienced with adefovir could arise with TDF.

68. Gilead also knew before marketing its first TDF Drug that while prodrugs allow the drug to be efficiently absorbed into the bloodstream and then converted into an active form within the body, the conversion of the TDF prodrug into free tenofovir outside the cell, and the presence of high levels of free tenofovir in the blood, endangers the kidneys.

69. TDF primarily damages the nephron tubule in the kidney, due to hyper-concentration of free tenofovir which results in cell death or dysfunction. If the tubule cells are dysfunctional or dead, they are unable or less able to perform the vital function of filtering waste and/or toxins and reabsorbing beneficial compounds. Moreover, because tenofovir is renally eliminated, patients are exposed to an increased concentration of tenofovir as the

kidneys become damaged.

70. Since scientists first synthesized TDF, studies have consistently shown that it could cause significant kidney and bone damage.

71. Gilead's preclinical studies of TDF showed that it could be toxic to kidneys and bones and that TDF exposure may cause bone toxicity in the form of softening of the bones (osteomalacia) and reduced bone mineral density.

72. Gilead also knew that the relatively high dose of TDF needed to achieve the desired therapeutic effect created a greater risk of toxic effects, and that bone and kidney toxicities were even more likely with the long-term use of TDF which was needed to combat a disease with no known cure.

E. Viread Goes to Market Despite Gilead's Knowledge that It Was Unreasonably Dangerous and Unsafe to Patients' Kidneys and Bones.

73. In May 2001, after demonstrating *TAF's* greater potency, concentration, efficacy, and bioavailability and despite being aware of the health risks posed by TDF, Gilead submitted its *TDF* design to the FDA for accelerated approval.

74. The approval process showed Gilead repeatedly defending TDF's weaknesses. The FDA repeatedly asked Gilead to conduct more studies and provide more data on TDF's risk of toxicity to bones and kidneys. The FDA's Division of Antiviral Products at one point stressed to Gilead "that they should be forthcoming with all tenofovir data."

75. In the course of pre-approval meetings, Gilead fought to have the FDA agree with its belief that "there is no evidence that tenofovir has a direct effect on bone." But, the FDA had documented sixteen bone fractures in clinical testing, and noted Gilead had

documented fifteen. The individual bone fracture data was omitted from Viread's package insert.

76. Viread was approved for sale on October 26, 2001. At that point, Gilead had not completed Phase III clinical studies and had excluded from its clinical trials people who had serious preexisting kidney dysfunction. And Gilead only studied Viread in treatment-experienced patients (those who had previously been treated for HIV)

77. Viread began almost immediately to take over the market for antiviral medications treating HIV infection. Sales grew from $225 million in 2001 to nearly $4 billion in 2008.

78. And almost immediately, patients ingesting Viread started experiencing the nephrotoxic effects of TDF.

79. In November 2001, less than one month after Viread entered the market, the first published case of TDF-associated acute renal failure occurred. Thereafter, additional reports of TDF- associated kidney damage, including but not limited to Fanconi syndrome, renal failure, renal tubular dysfunction, and nephrogenic diabetes insipidus, began to appear in the medical literature. Many of those adverse events occurred in patients without preexisting kidney dysfunction.

80. Gilead had to update its Viread labeling at least four times to describe the kidney damage patients experienced when taking TDF:

A. On December 2, 2002, Gilead added that patients had suffered renal impairment, including increased creatinine, renal insufficiency, kidney failure, and Fanconi syndrome, with Viread use;

B. On October 14, 2003, Gilead added more kidney disorders, including acute renal failure, proximal tubulopathy, and acute tubular necrosis;

C. On May 12, 2005, Gilead added nephrogenic diabetes insipidus; and

D. On March 8, 2006, Gilead added polyuria and nephritis to the list of renal and urinary disorders that patients had experienced while on TDF

81. Gilead's long-term clinical data also demonstrated that TDF was damaging patients' bones.

82. Several new studies presented at a February 2006 conference highlighted the frequency of nephrotoxicity in TDF-treated patients.

83. In 2007, Gilead scientists published an article discussing the company's knowledge of TDF safety issues over the first four years of TDF treatment. Gilead also reported that through April 2005 the most common serious adverse events reported to Gilead's post-marketing safety database were renal events, including renal failure, Fanconi syndrome, and serum creatinine increase.

84. Although this Gilead article demonstrates the company's clear and early knowledge of serious TDF toxicity in a significant number of patients, it downplayed the incidence of TDF-associated renal toxicity.

85. Moreover, even if Gilead's data accurately captured the percentage of patients experiencing serious renal adverse events (which it did not), it would still represent a very large number of patients who experienced significant health problems due to TDF toxicity.

86. In May 2007, Gilead had to update its labeling to recognize that TDF-associated renal damage also caused osteomalacia (softening of the bones) in patients.

87. During 2009-2011, studies continued to show that TDF caused a significant loss of renal function in HIV-infected patients.

88. With each passing year and each successive TDF product, Gilead learned even more about TDF's toxicity. Despite this knowledge, Gilead repeatedly designed the TDF Drugs to contain TDF as the tenofovir delivery mechanism rather than safer TAF.

F. FDA Approval of TAF

89. Although synthesized and put through pre-clinical trials in the late 1990s, 2000, and 2001, and then patented in 2004 and 2005, it was not until October 2010 that Gilead renewed development of TAF and not until November 5, 2014 that Gilead finally applied for approval from the FDA to sell a TAF-containing drug Genvoya.

90. In seeking FDA approval of Genvoya, Gilead told the FDA that TAF has better entry and concentration in HIV-target cells than TDF, thereby allowing the administration of smaller doses and reducing systemic tenofovir exposure, renal toxicity and bone effects, without sacrificing efficacy. This information was based on data obtained by Gilead more than a decade earlier before it had abruptly shelled its TAF design in pursuit of money.

91. Despite having discovered the benefits of TAF before 2001, Gilead repeatedly misrepresented TAF as "new." The benefits of TAF that Gilead described were known to Gilead years earlier. And the clinical results Gilead achieved with TAF would have been achieved years earlier but for Gilead's decision to slow-walk and withhold the safer TAF design purely for financial gain.

92. In 2015 and 2016 Gilead received FDA approval for three TAF-based drugs for the treatment of HIV: Genvoya, Odefsey and Descovy (collectively, the "TAF Drugs").

Specifically,

A. on November 5, 2015, the FDA approved Gilead's NDA for Genvoya, containing 10 mg TAF, 200 mg emtricitabine, 150 mg elvitegravir, and 150 mg cobicistat. The TDF-based counterpart to Genvoya is Stribild. Genvoya is identical to Stribild except for the substitution of TAF for TDF.

B. on March 1, 2016, the FDA approved Gilead's NDA for Odefsey, containing 25 mg TAF, 200 mg emtricitabine, and 25 mg rilpivirine. The TDF-based counterpart to Odefsey is Complera. Odefsey is identical to Complera except for the substitution of TAF for TDF.

C. on April 4, 2016, the FDA approved Gilead's NDA for Descovy, containing 25 mg TAF and 200 mg emtricitabine. The TDF-based counterpart to Descovy is Truvada. Descovy is identical to Truvada except for the substitution of TAF for TDF

93. As a result of its improved bone toxicity safety profile over TDF, the labels for Gilead's TAF-containing products no longer include bone effects in the Warnings and Precautions sections of the those labels.

94. Likewise, as a result of its improved renal safety profile over TDF, Gilead's TAF-containing products are better tolerated by patients with renal impairment.

95. Gilead's sales force has used data showing the superior safety profiles of TAF over TDF to convince doctors to switch patients from TDF-based to TAF-based products.

G. Gilead's Greed Motivates Concealment of a Safer Alternative

96. As TAF sat on the shelf after Gilead discontinued its development in 2004 until Gilead received FDA approval of its first TAF drug in 2015, Gilead continued to combine TDF with other drugs in order to further extend Gilead's monopoly profits and market share.

97. As prescriptions for TDF were growing along with Gilead's market share, Gilead's research continued to confirm TAF's diminished toxicity along with TDF's verified risks to bone and kidneys. But, Gilead did not publish this research, did not conduct clinical trials of TAF, did not change its prescribing information, and did not instruct its sales representatives to begin informing doctors that the toxicities associated with TDF could be eliminated with a new, better drug.

98. Gilead failed to take any of these steps because TDF sales were booming and Viread had begun to corner the market in antiviral treatments for HIV. Further, by keeping TDF as the focus of its antiviral offerings, Gilead knew it would reap future profits when it combined TDF with other patent-protected drugs to create newly-protected combination drugs that would prolong Gilead's ability to charge monopoly prices on all TDF-containing drugs.

99. Gilead's Atripla, approved for sale in 2006, had over $2.2B in U.S. sales in 2015. Complera, approved for sale in 2011, had almost $800M in U.S. sales in 2015. Truvada, approved for sale in July 2012, earned over $2B in 2015. And Stribild, approved for sale in August 2012, earned $1.5B in sales in 2015.

100. Indeed, the first TAF-containing drug, Genvoya, was not released for sale until November 2015. Gilead's patent on Viread was set to expire just over one year later in 2017.

101. Gilead shelved its TAF design in 2004 because it did not want to hurt TDF sales

by admitting that TDF is unreasonably and unnecessarily unsafe.

102. Gilead knew that by withholding the safer TAF design, it could extend the longevity of its HIV drug franchise and make billions two times over: first, with TDF medications until TDF patent expiration, which would begin by no later than 2018, and second, with TAF medications until TAF patent expiration as late as 2032.

103. But Gilead also knew that timing was key. While it wanted to delay the TAF-designed products to maximize profits on its TDF Drugs, it also knew that it had to get its TAF-based products on the market sufficiently in advance of TDF patent expiration. Gilead knew that once doctors switched their patients from TDF to TAF, doctors would be highly unlikely to switch their patients back to TDF-based regimens once generic TDF became available. By converting TDF prescriptions to TAF prescriptions (which cannot be automatically substituted at the pharmacy counter with a generic TDF product), Gilead could save a substantial percentage of sales from going generic.

104. Only once Gilead had realized billions in sales through most of the TDF patent life did Gilead create TAF-based versions of its prior TDF Drugs and work to convert its TDF Drug sales to TAF Drug sales.

105. Once TAF Drugs entered the market, Gilead successfully convinced a large percentage of doctors to switch from TDF-based to TAF-based regimens by highlighting TAF's improved safety profile with respect to bone and kidney toxicity—the very benefits that Gilead could have and should have incorporated into its product design from the beginning but withheld from patients with each successive TDF Drug for over a decade.

106. In addition, by delaying the filing of an NDA for its first TAF product, Gilead

knew that it was also delaying the entry of any generic manufacturer who could successfully challenge Gilead's TAF patents as invalid or not infringed. Due to its regulatory exclusivity, no generic manufacturer can seek to market a generic version of Genvoya until November 2019 and then, upon Gilead's suit against the generic, Gilead can automatically delay generic entry by up to an additional 30 months.

107. Gilead's tactics have allowed it to reap outsized profits and have led the New York Times to comment, "Gilead now is faced with figuring out what to do with all the cash it is generating."

108. In its 2015 earnings guidance, Gilead stated that it anticipated spending between 2.8 and 3 billion dollars on research and development, while earning a profit of roughly 18 billion dollars.

109. Gilead withheld its safer TAF design until it suited Gilead's bottom line at the expense of patients' health.

H. Gilead Failed to Adequately Warn about the Risks of TDF

110. Not only did Gilead hide a safer alternative design in an attempt to push other designs out of the market, it also failed to adequately warn Epstein and his doctors about the side effects associated with Atripla's and Gilead's toxicity and the need to routinely monitor all patients taking TDF in its advertising and patient labeling. Gilead was more concerned with increasing or maintaining TDF Drug sales in the U.S. by downplaying the safety risk and the need for careful, frequent monitoring of all patients than it was in safeguarding patients from the known risks of TDF toxicity.

111. Gilead's direct warnings to patients through package inserts or information

sheets downplayed the risk of TDF toxicity by, among other things, hiding risk information relative to the benefits of the drugs and suggesting that kidney and bone adverse events only occurred in, and monitoring was only necessary for, patients with risk factors for such injuries.

112. The TDF labels do not disclose that adverse kidney and bone events occurred in patients without pre-existing risk factors—which, combined with the warning to only routinely monitor patients at risk—gives the false impression that TDF is only harmful to people otherwise at risk for kidney and bone injuries. By failing to warn doctors as to the frequency of monitoring, Gilead delayed the diagnosis of TDF-associated harm, causing or enhancing injuries that could have been prevented or lessened through early detection.

113. Gilead's patient package inserts for Viread also did not warn of "new or worse kidney problems" until more than two years after Gilead had updated the warnings, albeit inadequately, in its Viread labeling to prescribing physicians. And Gilead waited even more years before it added the "new or worse kidney problems" disclosure to the Atripla patient package inserts.

114. Gilead similarly delayed disclosing to patients in the patient package inserts the need for their physicians to assess all patients' kidney function prior to initiating treatment with TDF. Because tenofovir is primarily cleared out of the body by the kidneys, a patient experiences even greater exposure to tenofovir as the kidneys become impaired—causing even greater harm. As a result, early detection is key to preventing serious, potentially irreversible renal injury. Frequent monitoring for TDF-induced toxicity of all patients' kidney function is also critical because patients are typically asymptomatic in the early stages and it is important to ensure that patients' kidneys are healthy enough to continue treatment or patients receive a

needed dose interval adjustment. Gilead, however, downplayed the risks of TDF and the need to monitor all patients in order to inflate sales.

115. From Viread's product approval on October 26, 2001 through May 20, 2007, Gilead's TDF labeling failed to warn doctors that all patients should be monitored for adverse kidney effects. During this time, Gilead only recommended monitoring patients taking TDF Drugs for renal adverse effects if patients were at risk for, or had a history of, renal impairment or if they were taking another nephrotoxic drug. This monitoring recommendation was woefully inadequate because, as Gilead was well aware, TDF-associated renal toxicity had harmed patients who were not at risk for, or did not have a history of, renal impairment.

116. Gilead also failed to include any warning about the need to monitor bone effects until October 14, 2003 and that warning was limited to patients with certain risk factors. Since then, Gilead has only suggested that doctors monitor, and only informs patients that monitoring may be necessary, for patients with certain risk factors for bone adverse effects.

117. Gilead failed to warn about the need for universal monitoring even though it knew that all patients taking TDF are at risk for renal and bone adverse effects and even after patients without pre-existing risk factors experienced kidney and bone effects.

118. By failing to warn doctors to monitor all patients for toxicities associated with TDF, Gilead delayed the diagnosis of TDF-associated harm, causing or enhancing injuries that would have been prevented or diminished through early detection.

119. Although Gilead added that warning to the Viread *prescriber* labeling in May 2007, it did not tell patients that "[y]our healthcare provider should do blood tests to check your kidneys before you start treatment" with TDF until August 2012 for Viread, May 2018 for

Truvada, July 2018 for Atripla, and January 2013 for Complera. At a minimum, Gilead was grossly negligent in failing to ensure that its warnings to patients were consistent with those it gave to doctors and the patient warnings it gave were consistent among its various TDF Drugs.

120. No TDF package insert or patient information sheet warns of the risk for fracture or bone breaks.

121. No TDF package insert or patient information sheet warns of the risks associated with long-term ingestion of Viread and Atripla, including but not limited to chronic kidney disease.

122. TDF-related patient information sheets suffer from the same inadequacy and tell patients only that they should inform their doctor if they have any pre-existing kidney or bone problems.

123. In addition to failing to adequately warn Epstein or his doctors of the risks to bones and kidneys associated with TDF, Gilead unlawfully minimized Viread's risks and overstated its efficacy through an extensive marketing campaign.

124. As Gilead stated in its 2002 10-K, its operations would suffer if Viread did not maintain or increase its market acceptance. Senior executed recognized that Gilead needed to overcome the perception in the medical community that Viread was like Gilead's previous HIV drugs and would likely cause kidney damage. Gilead stated in its 2002 filing that if additional safety issues were reported for Viread, this could "significantly reduce or limit our sales and adversely affect our results of operations."

125. Accordingly, Gilead dramatically increased its sales force and marketing budget, and trained its sales representatives to misrepresent Viread's safety profile.

126. At the direction of Gilead's senior management, Gilead representatives told doctors that Viread was a "miracle drug," "extremely safe," and "extremely well-tolerated" with "no toxicities."

127. The FDA sent Gilead a Warning Letter in March 2002, reprimanding Gilead for engaging in promotional activities that contained false and misleading statements in violation of the Federal Food, Drug and Cosmetic Act. The FDA further stated that Gilead unlawfully minimized Viread's risks, including with respect to kidney toxicity, and overstated its efficacy.

128. Despite this warning, Gilead continued to unlawfully promote Viread by minimizing its safety risks. In June 2003 Gilead instructed sales representatives during a sales training meeting to respond to anticipated physician concerns about Viread's nephrotoxicity by downplaying that many patients taking Viread had experienced the adverse effects of kidney toxicity, including renal failure, acute renal failure, and Fanconi syndrome.

129. The FDA issued another Warning Letter to Viread in July 2003, stating that Gilead's sales representatives had repeatedly omitted or minimized material facts regarding the safety profile of Viread. Among other things, the FDA required Gilead to retrain its sales force to ensure that Gilead's promotional activities complied with the Federal Food, Drug and Cosmetic Act and accompanying regulations. But Gilead had achieved its goal: rapidly increased Viread sales.

130. In later years, Gilead continued to downplay the risks of TDF-induced toxicity when promoting its TDF Drugs to doctors by misrepresenting the drug as safe, dismissing case reports of acute renal failure and other TDF-associated adverse events as purportedly unavoidable side effects of tenofovir in an otherwise "safe" drug, and discouraging doctors

from monitoring patients for drug-induced toxicity using more sensitive markers of kidney function.

131. Again, while Gilead's senior executive was claiming TDF was a risk-free, miracle drug, reports and studies recommended monitoring patients closely for early signs of toxicity, bone loss or kidney failure and further advised discontinuing treatment as swiftly as possible to avoid risks of permanent changes or damage.

132. Gilead knew that TDF toxicity led to kidney and bone damage, even in patients without pre-existing kidney or bone issues. Gilead had an obligation to share its exclusive knowledge of the risks and adequately warn of any known or knowable risks associated with the use of TDF. Instead, Gilead misrepresented the safety and benefits ofTDF and failed to provide prescribing physicians and their patients, including Plaintiff and his doctors, with the information they needed to safely and reasonably prescribe and take Gilead's drugs.

133. Gilead had a duty to design Viread in a manner that was not unreasonably dangerous. Instead, Gilead designed Viread with the prodrug TDF, a design it knew caused bone and kidney damage, so that they could maximize their profits and monopoly on TDF.

134. Plaintiff seeks general and punitive damages and seeks to hold Gilead accountable for its malicious and profit-driven refusal to design Viread in a safe and effective manner.

FRAUDULENT CONCEALMENT AND TOLLING

135. The running of any prescriptive period has been tolled by reason of Gilead's fraudulent concealment. Gilead had actual knowledge that its TDF Drugs were defective and a safer alternative existed and took affirmative steps to conceal the defect from Plaintiff Philip

Epstein and his physicians through its affirmative misrepresentations and omissions as to the true risks associated with the use of Viread and Atripla.

136. Gilead misrepresented that TAF was "new" despite knowing that it had discovered the benefits of TAF even before Viread was approved in 2001.

137. Gilead misrepresented the reasons that it shelved TAF in 2004, asserting that TAF could not be differentiated from TDF when it knew that TAF was, in fact, highly differentiated from TDF.

138. Gilead concealed that it halted development of TAF in 2004 in order to extend the lifecycle of its HIV product portfolio while patients were injured by TDF-induced kidney and bone toxicity.

139. For years, Gilead has publicized the pretense for its decision to terminate and then renew TAF development in order to conceal the existence of Plaintiff's claims.

140. Gilead concealed the true risk of kidney and bone injuries TDF posed to patients who did not have pre-existing risk factors for such injuries and concealed from U.S. doctors and patients what it knew about the need to monitor all patients for TDF associated toxicity.

141. Because of Gilead's misrepresentations and omissions, Plaintiff did not know and had no reason to suspect that Gilead's wrongdoing was the cause of his injuries and could not have discovered his claims.

142. 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 ameliorated those very side effects.

143. No reasonable person without prior risk factors for renal or bone harm taking

TDF- based drugs and experiencing kidney and bone toxicities would have suspected that Gilead failed to adequately warn them because the label misleadingly suggests that only patients with pre-existing risk factors were in danger.

144. No reasonable person would have suspected that Gilead provided stronger warnings to patients and doctors in the EU than it did in the U.S. for the exact same TDF products.

145. Gilead's misrepresentations and omissions would lead a reasonable person to believe that he did not have a claim for relief.

146. Because of Gilead's misrepresentations and omissions, neither Plaintiff nor any reasonable person would have have known or would have learned thorough reasonable diligence that the damage to Epstein's kidneys and bones was caused by Gilead's actions and omissions related to the production, marketing, and selling of Viread. Once Plaintiff suspected in 2019 that Gilead's wrongdoing was the cause of his injuries, he was diligent in trying to uncover the facts.

CLAIMS FOR RELIEF

COUNT I
STRICT PRODUCTS LIABILITY – DESIGN DEFECT
(Against Defendant Gilead)

147. Plaintiff re-alleges and incorporates the allegations made above as if fully set forth below.

148. At all times material hereto, Gilead was responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling its prescription drugs Viread and Atripla.

149. Viread and Atripla were expected to, and did, reach Plaintiff without substantial change to the condition in which they were produced, manufactured, sold, distributed, labeled, and marketed by Gilead.

150. Plaintiff ingested Viread and Atripla for an approved purpose and experienced bone and/or kidney injuries while taking Viread and Atripla.

151. Viread and Atripla were defective, unreasonably dangerous and unsafe for their intended purpose because they include TDF, which causes kidney and bone toxicity, as the design for delivering tenofovir to the body. This design defect existed in these drugs at the time they left Gilead's possession.

152. The risks of patient harm associated with TDF-induced kidney and bone toxicity were both known to and foreseeable to Gilead.

153. Gilead could have reduced or prevented the foreseeable harm and risks of harm to Plaintiff associated with TDF by adopting a reasonable and feasible alternative design. Gilead could have incorporated the safer TAF design, which it knew reduces the risks of kidney and bone toxicity and is safer than TDF, into Viread or Atripla before they were approved by the FDA.

154. Viread and Atripla were further defective, unreasonably dangerous in design and unsafe for their intended purpose because they failed to perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner. A reasonable consumer, such as Plaintiff, would not expect that these medications would destroy his kidneys and bones when used as intended or in a reasonably foreseeable manner. Gilead established the consumers,' including Plaintiff's expectations, for Viread and Atripla thereby

motivating Plaintiff to purchase Viread and Atripla.

155. Viread and Atripla are further defective, unreasonably dangerous and unsafe for their intended purpose because both before FDA approval and at the time the drugs left Gilead's control, Gilead had a safer alternative design for both Viread and Atripla.

156. Gilead knew, before it manufactured and distributed Atripla and Viread that TAF was more potent than TDF and reduced the risk of kidney and bone toxicity compared to TDF. Gilead also knew that it could reduce the dosage of tenofovir by substituting TAF Drugs and achieve the same antiviral response with less kidney and bone toxicity.

157. Gilead later utilized the TAF design instead of the TDF design in other FDA-approved products that are identical to Viread and/or Atripla except for the substitution of TAF for TDF.

158. Gilead markets its TAF-designed products as safer than Viread, Atripla and other TDF Drugs and advocates that doctors switch their patients from a TAF-designed to a TDF-designed product because of TAF's superior safety profile with respect to kidney and bone toxicity.

159. A drug product containing TAF could have and would have been FDA approved and on the market years earlier if Gilead had not purposefully shelved the TAF design for approximately six years in order to make more money.

160. A drug product containing TAF would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. Any foreseeable risks of harm posed by Viread or Atripla could have been reduced or avoided by the adoption of a reasonable alternative design by Gilead and

would have rendered the design of Atripla and Viread reasonably safe.

161. In short, when Gilead first manufactured and distributed Viread and/or Atripla, these TDF Drugs were not as safe as then-current technology could make them. As such, they were not "incapable of being made safe" for their intended and ordinary use.

162. Viread and Atripla are further defective, unreasonably dangerous and unsafe for their intended purpose because the risk, danger, and gravity of kidney damage, kidney failure, and bone loss, far outweighed any adverse effects on the utility of Viread or Atripla and far outweighed any possible burden on Gilead in adopting the alternative design.

163. The likelihood and severity of the kidney and bone injuries suffered by Plaintiff far outweighed Gilead's burden in taking safety measures to reduce or avoid the harm. Given the sheer number of people taking Viread, Atripla and other TDF Drugs, there was a high likelihood that TDF would injure a very large number of patients, and that a significant number of those injuries would be irreversible. Gilead's burden was small. Gilead had already discovered the safer TAF method of introducing tenofovir into the body before it sought FDA approval for Viread and Atripla and using the TAF design would have no adverse impact on the utility of those drugs.

164. Gilead knowingly utilized the TDF design rather than safer TAF to maximize profits on its portfolio of TDF profits and extend the lifecycle of its HIV franchise, which formed the backbone of Gilead's operations. Gilead withheld its safer TAF design to make more money at the expense of patients' health.

165. The benefit in promoting enhanced accountability through strict products liability outweighs the benefit of a product that Gilead should have and could have made safer

years earlier.

166. Gilead knew that ordinary patients like Plaintiff would use the TDF Drugs without knowledge of the hazards involved in such use. Viread and Atripla failed to perform as an ordinary consumer would expect.

167. Gilead placed Viread and Atripla on the market with a defect which was the legal cause of damage to Plaintiff.

168. Plaintiff's bone and kidney toxicity-related injuries were directly and proximately caused by the TDF used in the manufacture of Viread and Atripla.

169. As a direct and proximate result of the defective designs of Viread and Atripla, Plaintiff has and will continue to suffer severe and permanent injury and/or damage.

COUNT II
STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(Against Defendants Gilead, Packard, Pizarro and Grullon)

170. Plaintiff re-alleges and incorporates the allegations made above as if fully set forth below.

171. Gilead, as the manufacturer, seller and distributor of Viread and Atripla, knew that the TDF design it incorporated into the Viread and Atripla was associated with 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. Gilead's knowledge that Viread and Atripla harmed patients' kidneys and bones only grew with each year Viread and Atripla were on the market.

172. Gilead knew, before Viread or Atripla were approved by the FDA, that TAF is

safer than TDF in that it reduces the risks of kidney and bone toxicities associated with TDF. Despite knowing that TAF would reduce foreseeable harm to patients' kidneys and bones, Gilead repeatedly incorporated the TDF design into the TDF Drugs prior to FDA approval and prevented patients from taking a safer TAF-based product so Gilead could make more money.

173. The risks TDF posed to patients' kidneys and bones were known or knowable in light of the scientific and medical knowledge available at the time of manufacture, sale and distribution of Viread or Atripla.

174. The need to frequently monitor all TDF patients for kidney toxicity using more than one marker of kidney function to ensure the safe use of TDF was known or knowable in light of the scientific and medical knowledge available at the time of manufacture and distribution of the TDF Drugs.

175. Ordinary consumers and physicians would not have recognized the potential risks Viread or Atripla posed to patients' kidneys and bones.

176. Gilead failed to adequately warn Plaintiff and Plaintiff's physicians about the risks Viread and/or Atripla posed to patients' kidneys and bones, and the proper and safe use of the TDF Drugs and to instruct Plaintiff and Plaintiff' physicians on the safe use of Viread and Atripla (*i.e.*, use where doctors frequently monitored all Viread and Atripla patients for TDF-associated toxicity, including monitoring for kidney damage using more than one inadequate test.) Gilead knew to warn doctors to frequently monitor all patients for kidney damage using more than one inadequate test because it did so in the European Union.

177. Gilead's failure to adequately warn Plaintiff and Plaintiff' doctors about the need to monitor TDF Drug patients was compounded by Gilead's misrepresentations to doctors

during sales detailing and other promotional activities. Gilead's promotion of the TDF Drugs undermined the efficacy of its existing (inadequate) warnings.

178. When Gilead finally added a weak instruction regarding the monitoring of all patients for kidney damage, it only warned doctors to monitor patients for one insufficient marker of kidney dysfunction that was incapable of detecting many dangerous changes in kidney dysfunction, and failed to warn doctors to monitor Viread or Atripla patients on a frequent schedule.

179. Gilead owed a duty to warn Plaintiff because it was foreseeable to Gilead that patients like Plaintiff would ingest and consequently be endangered by Viread or Atripla.

180. The inadequate warnings and instructions Gilead did provide were minimized, eroded, and nullified by Gilead's improper promotion of Viread and Atripla to doctors.

181. The inadequate warnings and instructions directly and proximately caused Plaintiff' bone and kidney toxicity-related injuries.

COUNT III
NEGLIGENCE
(Against Defendants Gilead, Packard, Pizarro and Grullon)

182. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

183. Gilead researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced Viread and Atripla into the stream of commerce, and in the course of the same, directly advertised or marketed Viread to consumers or persons responsible for consumers, and therefore, had a duty to both Plaintiff

directly and his physicians to warn of risks associated with the use of the product.

184. Gilead has a duty to refrain from selling unreasonably dangerous products, including the duty to ensure that its pharmaceutical products do not cause patients to incorporates from foreseeable risks of harm.

185. Gilead has a duty to monitor the adverse effects associated with its pharmaceutical products, including the TDF Drugs.

186. Gilead has a continuing duty to warn of the adverse effects associated with its pharmaceutical products, including the TDF Drugs, to avoid reasonably foreseeable risks.

187. Gilead has a duty to identify any laboratory tests helpful in identifying adverse reactions and the recommended frequency with which such tests should be performed.

188. Gilead has a duty to exercise reasonable care when it undertakes affirmative acts for the protection of others.

189. Gilead owes these duties to Plaintiff because it was foreseeable to Gilead that patients like Plaintiff would ingest and consequently be endangered by its TDF Drugs.

190. Gilead knew that the TDF design it incorporated into the TDF Drugs was associated with 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. Gilead's knowledge that TDF harmed patients' kidneys and bones only grew with each year TDF was on the market. By the time Stribild entered the market, Gilead had more than a decade's worth of knowledge that TDF was toxic to kidneys and bones.

191. The Viread manufactured and/or supplied by Defendant was defective due to inadequate post-marketing warnings and/or instructions because, after Defendant knew or

should have known of the risks of chronic kidney disease from Viread use, they failed to provide adequate warnings to consumers of the product, including Plaintiff and Plaintiff physician(s), and continued to aggressively promote Viread as safe for kidneys and bones.

192. Due to the inadequate warnings regarding the risk of chronic kidney disease in patients without a history of kidney problems, Viread was in a defective condition and unreasonably dangerous at the time that it left the control of the Defendant. Defendant failed to adequately warn Plaintiff and Plaintiff's prescribing physician(s) of human and animal results in preclinical studies linking Viread to chronic kidney disease in patients with no prior kidney issues.

193. Gilead knew, before its first TDF Drug and every subsequent TDF Drug was approved by the FDA, that TAF is safer than TDF in that it reduces the risks of kidney and bone toxicities associated with TDF. Despite knowing that TAF would reduce foreseeable harm to patients' kidneys and bones, Gilead repeatedly incorporated the TDF design into the TDF Drugs prior to FDA approval and prevented patients from taking a safer TAF-based product so Gilead could make more money.

194. Based, inter alia, on its duty to monitor the adverse effects associated with Viread and Atripla, Gilead knew that the likelihood and severity of the harm associated with TDF was great. Thousands of patients experienced damage to their kidneys and bones as a result of TDF exposure—some of it severe and irreversible. The likelihood and severity of the kidney and bone injuries sufferred by patients like Plaintiff far outweighed Gilead's burden in taking safety measures to reduce or avoid the harm. Gilead had already designed the safer TAF method of introducing tenofovir into the body before it sought FDA approval for the TDF

Drugs. Gilead had also reduced the TAF dose when combined with cobicistat in Genvoya, when it was developing Stribild.

195. Gilead failed to exercise ordinary care in the design, manufacture, and sale of the TDF Drugs.

196. Gilead failed to use the amount of care in designing the TDF Drugs that a reasonably careful manufacturer would have used to avoid exposing patients to foreseeable risks of harm.

197. Gilead undertook to develop and market a safer TAF-designed product to sell to wholesalers and other direct purchasers of pharmaceuticals. Gilead recognized that its development and marketing of safer TAF-designed products was for the protection of patients like Plaintiff. By shelving 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 like Plaintiff. Gilead's failure to exercise reasonable care resulted in physical harm to Plaintiff.

198. Gilead failed to use the amount of care in warning about the risks and safe use of the TDF Drugs that a reasonably careful manufacturer would have used to avoid exposing patients to foreseeable risks of harm.

199. Gilead knew or reasonably should have known that the TDF Drugs were dangerous or likely to be dangerous when used in a reasonably foreseeable manner.

200. Gilead knew or reasonably should have known that Plaintiff and Plaintiff's physicians would not realize the danger posed by inadequate monitoring of patients taking TDF Drugs.

201. Gilead failed to adequately warn Plaintiff and Plaintiff's physicians about the need to monitor all patients taking the TDF Drugs. For years, Gilead failed to recommend that doctors monitor anyone other than patients "at risk" for TDF-induced kidney and/or bone injuries. When Gilead finally added a weak instruction regarding the monitoring of all patients for kidney damage, it only warned doctors to monitor patients for one insufficient marker of kidney dysfunction that was incapable of detecting many dangerous changes in kidney dysfunction, and failed to warn doctors to monitor TDF patients on a frequent schedule. Gilead's monitoring warnings with respect to "at risk" Viread, Truvada, Atripla, and Complera users and Stribild users were also inadequate because they failed to warn doctors to monitor patients on a specific, frequent schedule.

202. A reasonable manufacturer and seller under the same or similar circumstances would have instructed Plaintiff and Plaintiff' physicians on the safe use of the TDF Drugs, i.e., use where doctors frequently monitored all TDF patients for TDF-associated toxicity, including monitoring for kidney damage using more than one inadequate test. Gilead knew to warn doctors to frequently monitor all patients for kidney damage using more than one inadequate test because it did so in the European Union.

203. Gilead's failure to adequately warn Plaintiff and Plaintiff's doctors about the need to monitor TDF Drug patients was compounded by Gilead's misrepresentations to doctors during sales detailing and other promotional activities. Gilead's promotion of the TDF Drugs undermined the efficacy of its existing (inadequate) warnings.

204. Plaintiff was injured by using TDF in a reasonably foreseeable way.

205. The lack of adequate warnings was a substantial factor in causing Plaintiff's

injuries.

206. Had Gilead adequately warned Plaintiff's doctors, Plaintiff' doctors would have read and heeded such adequate warnings.

207. Plaintiff's properly warned physicians would have monitored Plaintiff more frequently and effectively. As a result, Plaintiff's properly warned physicians would have detected TDF toxicity earlier, thus preventing or lessening Plaintiff' injuries.

208. Plaintiff was injured as a direct and proximate result of Gilead's negligence.

209. Gilead's conduct constitutes gross negligence and willful misconduct.

210. By designing the TDF Drugs to contain TDF when it knew TDF harmed patients' kidneys and bones, and intentionally withholding the safer TAF design from patients, while failing to adequately warn of the known risks and safe use of TDF, Gilead acted in reckless disregard of, or with a lack of substantial concern for, the rights of others. By designing Stribild to contain 300 mg TDF when it knew to reduce the tenofovir prodrug dose with combined with cobicistat, Gilead acted in reckless disregard of, or with a lack of substantial concern for, the rights of others.

211. Gilead knew that its conduct would harm patients like Plaintiff but Gilead withheld its safer designs to make more money.

212. Had Plaintiff and his physicians been adequately warned of the side effects of Viread and Atripla, Plaintiff's prescribing physicians could have discussed the risk of chronic kidney disease with Plaintiff or they could have made the decision not to prescribe Viread or Atripla to Plaintiff and could have chosen to request other treatments or prescription medications.

213. However, Gilead's actions deprived Plaintiff and his physicians from making

educated decisions about his course of treatment.

214. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Gilead, Plaintiff was caused to suffer from the aforementioned injuries and damages.

COUNT IV
FRAUD
(Against Defendant Gilead)

215. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

216. This is an action for fraud against Defendant Gilead caused by its intentional omissions of, and misrepresentations about, material facts.

217. Gilead has a duty to exercise ordinary care in the design, manufacture, marketing, and sale of its pharmaceutical products, including Viread and Atripla.

218. Gilead has a duty to refrain from selling unreasonably dangerous products, including the duty to ensure that its pharmaceutical products do not cause patients to suffer from foreseeable risks of harm.

219. Gilead has a duty to monitor the adverse effects associated with its pharmaceutical products.

220. Gilead also owed a duty to speak and not conceal material facts because it was in possession of information about TDF and TAF that was not readily available to Plaintiff and Plaintiff's physicians.

221. Gilead owes these duties to Plaintiff because it was foreseeable to Gilead that patients like Plaintiff would ingest and consequently be endangered by the TDF Drugs.

222. Despite owing these duties to Plaintiff, Gilead made only partial representations about TDF and TAF to Plaintiff and Plaintiff's physicians while suppressing material facts, and actively concealed material information about TDF and TAF from Plaintiff and Plaintiff' physicians, including but not limited to the following:

(a) that a safer TAF design for delivering tenofovir into the body had been developed prior to seeking and receiving FDA approval for Viread and Atripla, but Gilead was instead promoting, marketing and selling its TDF Drugs anyway with the knowledge that TDF posed a significant and increased safety risk to patients' kidneys and bones;

(b) the toxicity associated with tenofovir was not unavoidable;

(c) the real reason Gilead abandoned its TAF design in 2004 was not because TAF could not be sufficiently differentiated from TDF; and

(d) The TAF design was shelved in order to maximize profits on its TDF-based products and extend its ability to profit on its HIV franchise for years to come

223. Gilead also made material misrepresentations about its TAF and TDF Drugs, including that that any tenofovir induced toxicity was rare and unavoidable and holding out TAF was "new" once Gilead finally introduced the safer TAF design over a decade later.

224. Gilead knew that this information was not readily available to Plaintiff and his doctors, and Plaintiff and his doctors did not have an equal opportunity to discover the truth. Plaintiff and his doctors had no practicable way of discovering the true state and timing of Gilead's knowledge.

225. Though its partial representations and concealment of material information about Viread and Atripla, Gilead intended to and did induce Plaintiff' doctors to prescribe, and Plaintiff to ingest, one or more of Viread and Atripla, thereby causing Plaintiff's injuries.

226. Plaintiff and their doctors justifiably relied on Gilead's representations and omissions regarding the state of development and toxicities associated with TAF and TDF.

227. Had Gilead disclosed that it was aware of, but intentionally withheld, the safer TAF mechanism for delivering tenofovir into the body, Plaintiff would have ingested TDF in a safer manner or switched to a different cART regimen.

228. Gilead further defrauded its customers by intentionally omitting adequate warnings 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. Gilead intentionally omitted an adequate monitoring warning in order to conceal the true risk of its TDF-based antiviral products, and to inflate sales by inducing doctors to prescribe, and patients like Plaintiff to consume, its TDF Drugs. By providing inadequate warnings that were contrary to those it gave with respect to the exact same drugs in the EU, Gilead partially disclosed material facts.

229. Had Gilead not omitted this information about the safe use of its drugs 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 Plaintiff. But for Gilead's omissions, Plaintiff would have consumed the TDF Drugs in a safer way or switched to a different drug regimen.

230. If Plaintiff had been adequately monitored for kidney and bone problems while

taking Viread and Atripla, he would not have been injured or his injuries would have been far less severe.

231. Plaintiff and his doctors justifiably relied on Gilead's product labeling and other representations, thereby causing Plaintiff's injuries.

COUNT V
VIOLATION OF FLORIDA UNFAIR AND DECEPTIVE TRADE PRACTICES ACT

232. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

233. This is an action for damages under Florida Statutes, Sections 501.201 - 501.213 commonly known as the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA").

234. FDUTPA was enacted "to protect the consuming public and legitimate enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive or unfair acts or practices in the conduct of any trade or commerce." Florida Statutes, Section 501.202(2).

235. Gilead is engaged in commerce in the State of Florida, as defined by Florida Statutes, Section 501.23(8), and is therefore subject to the provisions of FDUTPA. Gilead's TDF Drugs are "goods" within the meaning of FDUTPA.

236. Plaintiff is a "consumer" under Florida Statutes, Section 501.23(7) because he is a natural person who purchased Viread and Atripla for his personal use and as such is entitled to the protection of FDUTPA.

237. In selling its pharmaceuticals, Gilead was required to be honest in its dealings and not engage in any actions that had the effect of harming patients ingesting its drugs.

238. Pursuant to Florida Statutes, Section 501.24, "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

239. Gilead engaged in unconscionable, unfair, false, fraudulent, misleading, and deceptive acts and practices in connection with the sale and marketing of its TDF Drugs.

240. Gilead knew that a safer alternative to its TDF Drugs existed in the form of its TAF Drugs and yet it intentionally withheld them from the marketplace until it had maximized its profits and mislead its customers that no other safer alternative was available.

241. Gilead intentionally and unconscionably shelved its TDF drugs to wait until its patent exclusivity time periods had run.

242. When Gilead finally re-initiated development and FDA approval of its TAF Drugs, Gilead mislead patients, physicians and the public that this was a "new" design.

243. Gilead misrepresented its reasons for it halting development of TAF and omitted

244.concealed, and omitted material facts in its promotional, marketing, and labeling communications about the risks and benefits of the TDF Drugs to Plaintiff and Plaintiff' doctors, including but not limited to, that: 1) all TDF patients should be carefully and frequently monitored for adverse kidney and bone effects on a frequent schedule; and 2) Gilead had already developed the safer TAF design for delivering tenofovir into the body but nevertheless designed the TDF Drugs to contain TDF, and withheld the safer SAF design, in order to maximize profits on its TDF-based products and extend its ability to profit on its HIV franchise for years to come.

245. Gilead's conduct significantly impacted the public as actual or potential

consumers of Gilead's TDF Drugs. Hundreds of thousands of consumers in the U.S. have ingested one or more of the TDF Drugs and Gilead has directed its misleading marketing and promotional messages to the market generally. Consumers like Plaintiff are at an informational disadvantage and lack bargaining power relative to Gilead. Gilead's conduct has previously impacted other consumers and has significant potential to do so in the future.

246. Gilead's conduct was likely to mislead and did mislead reasonable consumers and members of the public.

247. Gilead's misrepresentations and omissions were material and affected Plaintiff and Plaintiff's doctors' conduct.

248. Gilead intended that others rely on its deceptive and misleading practices regarding its TDF Drugs.

249. Plaintiff and his doctors reasonably relied on Gilead's deceptive and misleading practices regarding its TDF Drugs.

250. Plaintiff's doctors prescribed, and Plaintiff ingested, Viread and Atripla Drugs in reliance on Gilead's unconscionable, false, misleading and/or deceptive acts, misrepresentations, and omissions.

251. Plaintiff was directly and proximately injured as a result of Gilead's deceptive conduct. But for Gilead's omissions and misrepresentations, Plaintiff would have ingested the TDF Drugs in a safer way—through better monitoring —thus preventing or reducing Plaintiff's injuries and monetary expenses in connection therewith.

252. Plaintiff suffered ascertainable losses as a result of Gilead's violations of the state consumer protection statutes alleged herein. Plaintiff will prove the full extent and amount

of their damages at trial.

COUNT VI
BREACH OF EXPRESS WARRANTY
(Against Defendant Gilead)

253. Plaintiff incorporates by reference each and every allegation made above, as if set forth fully here.

254. Defendant Gilead expressly warranted that Viread and Atripla were safe for their intended use and as otherwise described in this Complaint. Viread and Atripla did not conform to these express representations, including, but not limited to, the representation that it was well accepted in patient and animal studies, the representation that the drugs were safe, and the representation that the drugs did not have high and/or unacceptable levels of permanent or chronic side effects like kidney disease, and that it would improve health, maintain health, and potentially prolong life.

255. These express warranties represented by the Defendants were a part of the basis for Plaintiff's use of Viread and Atripla and Plaintiff and/or his physician relied on these warranties in deciding to prescribe and use Viread and Atripla.

256. At the time they made the express warranties, the Defendants had knowledge of the purpose for which the Viread and Atripla were to be used and warrantied them to be in all respects safe, effective, and proper for such purpose.

257. Viread and Atripla do not conform to these express representations because they are not safe or effective and may produce serious side effects to patients' kidneys and bones.

258. As a result of the foregoing breach of express warranties plaintiff was caused to suffer damage to his bones and kidneys, as well as other severe and personal injuries which

were permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

COUNT VII
BREACH OF IMPLIED WARRANTY
(Against Defendant Gilead)

259. Plaintiff incorporates by reference each and every allegation made above, as if set forth fully here.

260. Viread and Atripla were defective because they were manufactured unreasonably dangerously, as described above. Had Plaintiff or his physicians known of the defect, he would not have been prescribed or ingested Viread or Atripla.

261. Defendant was aware of the substantial risks from using Viread and Atripla but failed to fully disclose those risks to the Plaintiff or his physicians.

262. Had Plaintiff or his physicians been made aware of the defects contained in Viread and Atripla, he would not have purchased either Viread or Atripla. This characteristic rendered Viread and Atripla unfit for their intended purposes.

263. Viread and Atripla were defective because they were not reasonably fit for the specific purpose for which Gilead knowingly sold them and for which, in reliance on the judgment of Gilead, Plaintiff purchased Viread and Atripla.

DAMAGES

264. As a result of Defendants' acts, omissions, and failures described herein, Plaintiff Philip B. Epstein has sustained substantial injuries, permanent disability, and damages, including, but not limited to damages to Plaintiff's kidneys and bones.

265. As a result of his injuries, Plaintiff has and will sustain the following nonexclusive damages: physical injuries; past, present and future emotional distress; loss of enjoyment of life; past, present and future mental pain and suffering; inconvenience; past, present and future physical pain, suffering and disability; past, present and future medical expenses; economic damages; and other damages to be proven at the trial of this matter.

PUNITIVE DAMAGES

266. Defendant Gilead's conduct, as described above, was extreme, outrageous, oppressive, fraudulent, and/or malicious. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public in order to protect Gilead's monopoly profits and continue to corner the market for antiviral medication. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, including Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests this Court enter an Order and Judgment against Defendants:

A. Awarding Plaintiff actual, compensatory, and/or statutory damages in an amount to be proven at trial;

B. Declaring, adjudging, and decreeing the conduct of Gilead as alleged herein to be unlawful, unfair, and/or deceptive and otherwise in violation of the law

C. Awarding Plaintiff punitive and exemplary damages in an amount to be determined at trial;

D. Awarding Plaintiff restitution and restitutionary disgorgement to restore ill-gotten gains received by Gilead as a result of the unfair, wrongful, and deceptive conduct alleged herein;

E. Awarding Plaintiff the costs of bringing this action and reasonable attorneys' fees; and

F. Granting any and all such other and further relief as the Court deems necessary, just, and proper.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury on all issues.

Dated this 24th day of September, 2019.

Respectfully submitted,

George W. Kramer, Esq.
Debra D. Klingsberg, Esq.
Tel (561) 235-6199
Facsimile (561) 496-5499
gkramerlaw@gmail.com
dklingsberglaw@gmail.com

BY: /s/George W. Kramer
George W. Kramer, Esq.
Florida Bar No.: 0104214
Debra D. Klingsberg, Esq.
Florida Bar No. 767921

Filing # 96213443 E-Filed 09/24/2019 03:02:13 PM

IN THE CIRCUIT COURT OF THE FIFTEENTH JUDICIAL CIRCUIT IN AND FOR PALM BEACH COUNTY, FLORIDA

PHILIP B. EPSTEIN,

Plaintiff ,

v.

GILEAD SCIENCES, INC., CHARLES PACKARD, CESAR PIZARRO, and LUIS GRULLON,

Defendants.

_____/

CASE NO.

JURY TRIAL DEMANDED

THE STATE OF FLORIDA:

To Each Sheriff of the State:

GREETINGS:

YOU ARE HEREBY COMMANDED to serve this Summons and a copy of the Complaint or Petition in this action on defendant:

Gilead Sciences, Inc.
% Registered Agent: C T CORPORATION SYSTEM
1200 SOUTH PINE ISLAND ROAD
PLANTATION, FL 33324

Each Defendant is hereby required to serve written defenses to said Complaint or Petition on Plaintiff's attorneys, whose names and address is:

George W. Kramer, Esquire
Debra D. Klingsberg, Esquire
16215 Cabernet Drive
Delray Beach, FL 33446
Telephone: (561) 235-6199
gkramerlaw@gmail.com
dklingsberglaw@gmail.com

within twenty (20) days after service of this Summons on that Defendant, exclusive of the day of service, and to file the original of said written defenses with the clerk of said Court either before service on Plaintiff's attorney or immediately thereafter.

If a Defendant fails to do so, a default will be entered against that Defendant for the relief demanded in the Complaint or Petition.

DATED on Sep 26 2019

, As Clerk of the Court

By: Blake Smith
As Deputy Clerk

BLAKE SMITH

IMPORTANT

A lawsuit has been filed against you. You have 20 calendar days after this summons is served on you to file a written response to the attached complaint with the clerk of this court. A phone call will not protect you. Your written response, including the case number given above and the names of the parties, must be filed if you want the court to hear your side of the case. If you do not file your response on time, you may lose the case, and your wages, money, and property may thereafter be taken without further warning from the court. There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may call an attorney referral service or a legal aid office (listed in the phone book).

If you choose to file a written response yourself, at the same time you file your written response to the court you must also mail or take a copy of your written response to the "Plaintiff/Plaintiff's Attorney" named below.

IMPORTANTE

Usted ha sido demandado legalmente. Tiene 20 dias, contados a partir del recibo de esta notificacion, para contestar la demanda adjunta, por escrito, y presentarla ante este tribunal. Una llamada telefonica no lo protegera. Si usted desea que el tribunal considere su defensa, debe presentar su respuesta por escrito, incluyendo el numero del caso y los nombres de las partes interesadas. Si usted no contesta la demanda a tiempo, pudiese perder el caso y podria ser despojado de sus ingresos y propiedades, o privado de sus derechos, sin previo aviso del tribunal. Existen otros requisitos legales. Si lo desea, puede usted consultar a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a una de las oficinas de asistencia legal que aparecen en la guia telefonica.

Si desea responder a la demanda por su cuenta, al mismo tiempo en que presenta su respuesta ante el tribunal, debera usted enviar por correo o entregar una copia de su respuesta a la persona denominada abajo como "Plaintiff/Plaintiff's Attorney" (Demandante o Abogado del Demandante).

IMPORTANT

Des poursuites judiciares ont ete entreprises contre vous. Vous avez 20 jours consecu-tifs a partir de la date de l'assignation de cette citation pour deposer une reponse ecrite a la plainte ci- jointe aupres de ce tribunal. Un simple coup de telephone est insuffisant pour vous proteger. Vous etes obliges de deposer votre reponse ecrite, avec mention du numero de dossier ci-dessus et du nom des parties nommees ici, si vous souhaitez que le tribunal entende votre cause. Si vous ne deposez pas votre reponse ecrite dans le relai requis, vous risquez de perdre la cause ainsi que votre salaire, votre argent, et vos biens peuvent etre saisis par la suite, sans aucun preavis ulterieur du tribunal. Il y a d'autres obligations juridiques et vous pouvez requerir les services immediats d'un avocat. Si vous ne connaissez pas d'avocat, vous pourriez telephoner a un service de reference d'avocats ou a un bureau d'assistance juridique (figurant a l'annuaire de telephones).

Si vous choisissez de deposer vous-meme une reponse ecrite, il vous faudra egale-ment, en meme temps que cette formalite, faire parvenir ou expedier une copie de votre reponse ecrite au "Plaintiff/Plaintiff's Attorney" (Plaignant ou a son avocat) nomme ci-dessous.

Plaintiff's Attorneys: George W. Kramer, Esquire
Debra D. Klingsberg, Esquire
16215 Cabernet Drive
Delray Beach, FL 33446
Florida Bar No.: 0104214

VERIFIED RETURN OF SERVICE

State of FLROIDA **County of PALM BEACH** **Circuit Court**

Case Number: 50 2019 CA 12348 XXXX MB AK

Plaintiff:
PHILIP B. EPSTEIN,

vs.

Defendant:
GILEAD SCIENCES, INC., et al.,

For:
GEORGE W. KRAMER
GEORGE W. KRAMER, ESQUIRE
16215 Cabernet Drive
Delray Beach, FL 33446

Received by LARGO INVESTIGATIONS, INC. on the 27th day of September, 2019 at 7:00 pm to be served on **GILEAD SCIENCES, INC., Registered Agent: CT Corporation System, 1200 South Pine Island Road, Plantation, FL 33324**.

I, Richard E. Largo, do hereby affirm that on the **1st day of October, 2019** at **3:10 pm, I:**

served a **CORPORATION** by delivering a true copy of the **SUMMONS AND COMPLAINT** with the date and hour of service endorsed thereon by me, to: **Donna Moch Employee of CT Corporation System as Registerd Agent** for **GILEAD SCIENCES, INC.,**, at the address of: **1200 South Pine Island Road, Plantation, FL 33324**, and informed said person of the contents therein, in compliance with state statutes.

Description of Person Served: Age: 40+, Sex: F, Race/Skin Color: White, Height: 5'2", Weight: 140, Hair: Salt & Pepper, Glasses: N

I Acknowledge that I am authorized to serve process. In good standing in the jurisdiction wherein this process was served and I have no interest in the above action. Under penalties of perjury, I declare that I have read the foregoing documents and that the facts stated in it are true, F.S. 92.525 (2), no Notary is required.

Richard E. Largo
S P S # 381

LARGO INVESTIGATIONS, INC.
9369 Aegean Drive
Boca Raton, FL 33496
(561) 482-5757

Our Job Serial Number: LII-2019002232

IN THE CIRCUIT COURT OF THE FIFTEENTH JUDICIAL CIRCUIT IN AND FOR PALM BEACH COUNTY, FLORIDA

PHILIP B. EPSTEIN,

Plaintiff ,

v.

GILEAD SCIENCES, INC., CHARLES PACKARD, CESAR PIZARRO, and LUIS GRULLON,

Defendants.

_____/

CASE NO.

JURY TRIAL DEMANDED

THE STATE OF FLORIDA:

To Each Sheriff of the State:

GREETINGS:

YOU ARE HEREBY COMMANDED to serve this Summons and a copy of the Complaint or Petition in this action on defendant:

Cesar Pizarro
15120 SW 46th Ter.
Miami, FL 33185

Each Defendant is hereby required to serve written defenses to said Complaint or Petition on Plaintiff's attorneys, whose names and address is:

George W. Kramer, Esquire
Debra D. Klingsberg, Esquire
16215 Cabernet Drive
Delray Beach, FL 33446
Telephone: (561) 235-6199
gkramerlaw@gmail.com
dklingsberglaw@gmail.com

within twenty (20) days after service of this Summons on that Defendant, exclusive of the day of service, and to file the original of said written defenses with the clerk of said Court either before service on Plaintiff's attorney or immediately thereafter.

If a Defendant fails to do so, a default will be entered against that Defendant for the relief demanded in the Complaint or Petition.

DATED on Sep 26 2019

, As Clerk of the Court

By: Blake Smith
As Deputy Clerk BLAKE SMITH

IMPORTANT

A lawsuit has been filed against you. You have 20 calendar days after this summons is served on you to file a written response to the attached complaint with the clerk of this court. A phone call will not protect you. Your written response, including the case number given above and the names of the parties, must be filed if you want the court to hear your side of the case. If you do not file your response on time, you may lose the case, and your wages, money, and property may thereafter be taken without further warning from the court. There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may call an attorney referral service or a legal aid office (listed in the phone book).

If you choose to file a written response yourself, at the same time you file your written response to the court you must also mail or take a copy of your written response to the "Plaintiff/Plaintiff's Attorney" named below.

IMPORTANTE

Usted ha sido demandado legalmente. Tiene 20 dias, contados a partir del recibo de esta notificacion, para contestar la demanda adjunta, por escrito, y presentarla ante este tribunal. Una llamada telefonica no lo protegera. Si usted desea que el tribunal considere su defensa, debe presentar su respuesta por escrito, incluyendo el numero del caso y los nombres de las partes interesadas. Si usted no contesta la demanda a tiempo, pudiese perder el caso y podria ser despojado de sus ingresos y propiedades, o privado de sus derechos, sin previo aviso del tribunal. Existen otros requisitos legales. Si lo desea, puede usted consultar a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a una de las oficinas de asistencia legal que aparecen en la guia telefonica.

Si desea responder a la demanda por su cuenta, al mismo tiempo en que presenta su respuesta ante el tribunal, debera usted enviar por correo o entregar una copia de su respuesta a la persona denominada abajo como "Plaintiff/Plaintiff's Attorney" (Demandante o Abogado del Demandante).

IMPORTANT

Des poursuites judiciares ont ete entreprises contre vous. Vous avez 20 jours consecu-tifs a partir de la date de l'assignation de cette citation pour deposer une reponse ecrite a la plainte ci- jointe aupres de ce tribunal. Un simple coup de telephone est insuffisant pour vous proteger. Vous etes obliges de deposer votre reponse ecrite, avec mention du numero de dossier ci-dessus et du nom des parties nommees ici, si vous souhaitez que le tribunal entende votre cause. Si vous ne deposez pas votre reponse ecrite dans le relai requis, vous risquez de perdre la cause ainsi que votre salaire, votre argent, et vos biens peuvent etre saisis par la suite, sans aucun preavis ulterieur du tribunal. Il y a d'autres obligations juridiques et vous pouvez requerir les services immediats d'un avocat. Si vous ne connaissez pas d'avocat, vous pourriez telephoner a un service de reference d'avocats ou a un bureau d'assistance juridique (figurant a l'annuaire de telephones).

Si vous choisissez de deposer vous-meme une reponse ecrite, il vous faudra egale-ment, en meme temps que cette formalite, faire parvenir ou expedier une copie de votre reponse ecrite au "Plaintiff/Plaintiff's Attorney" (Plaignant ou a son avocat) nomme ci-dessous.

Plaintiff's Attorneys: George W. Kramer, Esquire
Debra D. Klingsberg, Esquire
16215 Cabernet Drive
Delray Beach, FL 33446
Florida Bar No.: 0104214

VERIFIED RETURN OF SERVICE

State of FLROIDA **County of PALM BEACH** **Circuit Court**

Case Number: 50 2019 CA 12348 XXXX MB AK

Plaintiff:
PHILIP B. EPSTEIN,

vs.

Defendant:
GILEAD SCIENCES, INC., et al.,

For:
GEORGE W. KRAMER
GEORGE W. KRAMER, ESQUIRE
16215 Cabernet Drive
Delray Beach, FL 33446

Received by LARGO INVESTIGATIONS on the 29th day of September, 2019 at 2:52 pm to be served on **CESAR PIZARRO, 15120 S.W. 46th Terrace, Miami, FL 33185.**

I, GREG SCHULTE, do hereby affirm that on the **9th day of October, 2019** at **6:55 pm, I:**

SUBSTITUTE - RESIDENTIAL: served by delivering y true copy of the **SUMMONS AND COMPLAINT** with the date and hour of service endorsed thereon by me, to: **ANGIE PIZARRO** as **WIFE/CO-RESIDENT at the address of 15120 S.W. 46th Terrace, Miami, FL 33185**, of the within named person's usual place of abode, who resides therein, who is fifteen (15) years of age or older and informed said person of the contents therein, in compliance with state statutes.

Military Status: Based upon inquiry of party served, Defendant is not in the military service of the United States of America.

Marital Status: Based upon inquiry of party served, Defendant is married.

Description of Person Served: Age: 40+, Sex: F, Race/Skin Color: WHITE, Height: 5'4", Weight: 110, Hair: BROWN, Glasses: N

I CERTIFY THAT I AM OVER THE AGE OF 18, HAVE NO INTEREST IN THE ABOVE ACTION, AND THAT I AM A CERTIFIED PROCESS SERVER, IN GOOD STANDING, IN THE JUDICIAL CIRCUIT IN WHICH THE PROCESS WAS SERVED. "UNDER PENALTY OF PERJURY, I DECLARE THAT I HAVE READ THE FOREGOING (DOCUMENT) AND THAT THE FACTS STATED IN IT ARE TRUE, 92.525.

GREG SCHULTE
CPS #245

LARGO INVESTIGATIONS
9369 Aegean Drive
Boca Raton, FL 33496
(561) 482-5757

Our Job Serial Number: LII-2019002234

15205

IN THE CIRCUIT COURT OF THE FIFTEENTH JUDICIAL CIRCUIT IN AND FOR PALM BEACH COUNTY, FLORIDA

PHILIP B. EPSTEIN,

Plaintiff ,

v.

GILEAD SCIENCES, INC., CHARLES PACKARD, CESAR PIZARRO, and LUIS GRULLON,

Defendants.

_____/

CASE NO.

JURY TRIAL DEMANDED

THE STATE OF FLORIDA:

To Each Sheriff of the State:

GREETINGS:

YOU ARE HEREBY COMMANDED to serve this Summons and a copy of the Complaint or Petition in this action on defendant:

Luis Grullon
351 NE 117th Street
Miami, FL 33161

Each Defendant is hereby required to serve written defenses to said Complaint or Petition on Plaintiff's attorneys, whose names and address is:

George W. Kramer, Esquire
Debra D. Klingsberg, Esquire
16215 Cabernet Drive
Delray Beach, FL 33446
Telephone: (561) 235-6199
gkramerlaw@gmail.com
dklingsberglaw@gmail.com

within twenty (20) days after service of this Summons on that Defendant, exclusive of the day of service, and to file the original of said written defenses with the clerk of said Court either before service on Plaintiff's attorney or immediately thereafter.

If a Defendant fails to do so, a default will be entered against that Defendant for the relief demanded in the Complaint or Petition.

DATED on Sep 26 2019

, As Clerk of the Court

By: Blake Smith
As Deputy Clerk BLAKE SMITH

IMPORTANT

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IMPORTANTE

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Si desea responder a la demanda por su cuenta, al mismo tiempo en que presenta su respuesta ante el tribunal, debera usted enviar por correo o entregar una copia de su respuesta a la persona denominada abajo como "Plaintiff/Plaintiff's Attorney" (Demandante o Abogado del Demandante).

IMPORTANT

Des poursuites judiciares ont ete entreprises contre vous. Vous avez 20 jours consecu-tifs a partir de la date de l'assignation de cette citation pour deposer une reponse ecrite a la plainte ci- jointe aupres de ce tribunal. Un simple coup de telephone est insuffisant pour vous proteger. Vous etes obliges de deposer votre reponse ecrite, avec mention du numero de dossier ci-dessus et du nom des parties nommees ici, si vous souhaitez que le tribunal entende votre cause. Si vous ne deposez pas votre reponse ecrite dans le relai requis, vous risquez de perdre la cause ainsi que votre salaire, votre argent, et vos biens peuvent etre saisis par la suite, sans aucun preavis ulterieur du tribunal. Il y a d'autres obligations juridiques et vous pouvez requerir les services immediats d'un avocat. Si vous ne connaissez pas d'avocat, vous pourriez telephoner a un service de reference d'avocats ou a un bureau d'assistance juridique (figurant a l'annuaire de telephones).

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Plaintiff's Attorneys: George W. Kramer, Esquire
Debra D. Klingsberg, Esquire
16215 Cabernet Drive
Delray Beach, FL 33446
Florida Bar No.: 0104214

VERIFIED RETURN OF SERVICE

State of FLROIDA **County of PALM BEACH** **Circuit Court**

Case Number: 50 2019 CA 12348 XXXX MB AK

Plaintiff:
PHILIP B. EPSTEIN,

vs.

Defendant:
GILEAD SCIENCES, INC., et al.,

For:
GEORGE W. KRAMER
GEORGE W. KRAMER, ESQUIRE
16215 Cabernet Drive
Delray Beach, FL 33446

Received by LARGO INVESTIGATIONS on the 29th day of September, 2019 at 2:52 pm to be served on **LUIS GRULLON, 351 N.E. 117th Street, Miami, FL 33161.**

I, DANNY MENDEZ, do hereby affirm that on the **9th day of October, 2019 at 7:00 pm, I:**

INDIVIDUAL/PERSONAL: served by delivering a true copy of the **SUMMONS AND COMPLAINT** to: **LUIS GRULLON** at the address of: **351 N.E. 117th Street, Miami, FL 33161** with the date and hour of service endorsed thereon by me, and informed said person of the contents therein, in compliance with state statutes.

Military Status: Based upon inquiry of party served, Defendant is not in the military service of the United States of America.

Marital Status: Based upon inquiry of party served, Defendant is married.

Description of Person Served: Age: 40+, Sex: M, Race/Skin Color: HISPANIC, Height: 5'9", Weight: 180, Hair: BLACK, Glasses: N

I CERTIFY THAT I AM OVER THE AGE OF 18, HAVE NO INTEREST IN THE ABOVE ACTION, AND THAT I AM A CERTIFIED PROCESS SERVER, IN GOOD STANDING, IN THE JUDICIAL CIRCUIT IN WHICH THE PROCESS WAS SERVED. "UNDER PENALTY OF PERJURY, I DECLARE THAT I HAVE READ THE FOREGOING (DOCUMENT) AND THAT THE FACTS STATED IN IT ARE TRUE, 92.525.

DANNY MENDEZ
CPS #1265

LARGO INVESTIGATIONS
9369 Aegean Drive
Boca Raton, FL 33496
(561) 482-5757

Our Job Serial Number: LII-2019002233

15206

IN THE CIRCUIT COURT OF THE FIFTEENTH JUDICIAL CIRCUIT IN AND FOR PALM BEACH COUNTY, FLORIDA

PHILIP B. EPSTEIN,

Plaintiff ,

v.

GILEAD SCIENCES, INC., CHARLES PACKARD, CESAR PIZARRO, and LUIS GRULLON,

Defendants.

_____/

CASE NO.

JURY TRIAL DEMANDED

THE STATE OF FLORIDA:

To Each Sheriff of the State:

GREETINGS:

YOU ARE HEREBY COMMANDED to serve this Summons and a copy of the Complaint or Petition in this action on defendant:

Charles Packard
291 Sea Island Road
St. Simons Island, GA 31522

Each Defendant is hereby required to serve written defenses to said Complaint or Petition on Plaintiff's attorneys, whose names and address is:

George W. Kramer, Esquire
Debra D. Klingsberg, Esquire
16215 Cabernet Drive
Delray Beach, FL 33446
Telephone: (561) 235-6199
gkramerlaw@gmail.com
dklingsberglaw@gmail.com

within twenty (20) days after service of this Summons on that Defendant, exclusive of the day of service, and to file the original of said written defenses with the clerk of said Court either before service on Plaintiff's attorney or immediately thereafter.

If a Defendant fails to do so, a default will be entered against that Defendant for the relief demanded in the Complaint or Petition.

DATED on Sep 26 2019

, As Clerk of the Court

By: Blake Smith
As Deputy Clerk BLAKE SMITH

IMPORTANT

A lawsuit has been filed against you. You have 20 calendar days after this summons is served on you to file a written response to the attached complaint with the clerk of this court. A phone call will not protect you. Your written response, including the case number given above and the names of the parties, must be filed if you want the court to hear your side of the case. If you do not file your response on time, you may lose the case, and your wages, money, and property may thereafter be taken without further warning from the court. There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may call an attorney referral service or a legal aid office (listed in the phone book).

If you choose to file a written response yourself, at the same time you file your written response to the court you must also mail or take a copy of your written response to the "Plaintiff/Plaintiff's Attorney" named below.

IMPORTANTE

Usted ha sido demandado legalmente. Tiene 20 dias, contados a partir del recibo de esta notificacion, para contestar la demanda adjunta, por escrito, y presentarla ante este tribunal. Una llamada telefonica no lo protegera. Si usted desea que el tribunal considere su defensa, debe presentar su respuesta por escrito, incluyendo el numero del caso y los nombres de las partes interesadas. Si usted no contesta la demanda a tiempo, pudiese perder el caso y podria ser despojado de sus ingresos y propiedades, o privado de sus derechos, sin previo aviso del tribunal. Existen otros requisitos legales. Si lo desea, puede usted consultar a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a una de las oficinas de asistencia legal que aparecen en la guia telefonica.

Si desea responder a la demanda por su cuenta, al mismo tiempo en que presenta su respuesta ante el tribunal, debera usted enviar por correo o entregar una copia de su respuesta a la persona denominada abajo como "Plaintiff/Plaintiff's Attorney" (Demandante o Abogado del Demandante).

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Plaintiff's Attorneys: George W. Kramer, Esquire
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