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SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF SAN MATEO

CHARLENE ALBERTY, ARMANDO ARTEAGA, DEBORAH AYALA, JUSTIN BRALY, JERRY BRIGHTMAN, LATEEFAH CAESAR, JOSE CARBAJAL CRUZ, KENNETH FITZ, ALFREDO GALLEGOS, RAMON GARY, PAMELA GLOVER, JAVIER GOMEZ, RICHARD GOODWIN, JOHNNY GREEN, LEON GREEN, PHILLIP GREENBERG, GREGORY HART, TANIA HOUSTON, JERAL HUTCHINSON, LISA JACKSON-GRAY, ROBERT JACOBSEN, THEODUS KENDRICK, CHARLES LATHAM, LEARDIS LEONARD, MARK MALLERY, SHEILA MIDGET, WILLIE C. MORRIS, JACQURIA NELSON, BENJAMIN PATTERSON, SANDRA POLK, ROBERT PURELL, JULIE REYES, NANCY RODRIGUEZ, ARMANDO SOLA, REUBEN TUCKER, LASHAWN TYNES, DAVID WILLIAMS, BOBBY WILLIAMS, JAMES WOODS, and ARTURO ZAMORA.

Plaintiffs,

v.

GILEAD SCIENCES, INC.

Defendant.

19CIV02680

CASE NO. _____

COMPLAINT FOR DAMAGES

1. STRICT PRODUCTS LIABILITY
2. NEGLIGENCE
3. FRAUD AND CONCEALMENT

DEMAND FOR JURY TRIAL

Plaintiffs bring this personal injury action against Defendant Gilead Sciences, Inc. ("Gilead") to recover monetary damages and other remedies for violations of California law.

INTRODUCTION

1. This action arises from preventable injuries Plaintiffs sustained as a result of ingesting the prescription drugs Viread, Truvada, Atripla, Complera, and/or Stribild (collectively, "TDF

drugs"), which were designed, manufactured, and marketed by Gilead for the treatment or prevention of Human Immunodeficiency Virus-1 ("HIV") infection.

2. Gilead has made billions from the sale of HIV antiretroviral drugs containing highly toxic doses of tenofovir disoproxil fumarate ("TDF"), a form of the compound tenofovir that Gilead knew was toxic to patients' kidneys and bones.

3. Before Gilead began selling its first TDF drug, Viread, in 2001, the corporation knew TDF toxicity caused kidney and bone damage in patients without pre-existing kidney or bone issues. Gilead also knew that a 300 mg dose of TDF – the exact dosage in each of its five TDF drugs – created a greater risk of toxicity and injury and that these toxicities become more prevalent with long-term use of TDF. By the time Gilead designed its last TDF drug, Stribild, in 2012, it had over ten years' worth of cumulative evidence of the safety risks posed by TDF.

4. Despite this knowledge, Gilead falsely promoted Viread as a "miracle drug" with "no toxicities" that was both "benign" and "extremely safe." The Food and Drug Administration ("FDA") formally warned Gilead several times that the corporation was misleading the public over TDF's risks. The FDA even required Gilead to retrain its sales representatives "due to the significant public health and safety concerns" raised by their repeated false statements about TDF.

5. Regulators abroad also reprimanded Gilead for misleading patients and clients about TDF. Reports of kidney failure and other injuries led European drug regulators to ask Gilead in 2006 to remind doctors to monitor patients' renal function. Gilead had long warned doctors in the European Union to monitor all TDF drug patients for multiple markers of TDF toxicity on a frequent, specified schedule. Inexplicably, Gilead failed to provide U.S. doctors with those same warnings for identical TDF drugs, thus preventing doctors in Gilead's own backyard from detecting early signs of TDF toxicity.

6. In addition to misleading physicians and patients about TDF's toxicity, Gilead withheld from the public a safer alternative HIV antiretroviral medication. In fact, Gilead scientists

had reformulated tenofovir to reduce its toxicity even before TDF was first approved by the FDA in 2001. This reformulation—one of many Gilead discovered around the same time it discovered TDF—tenofovir alafenamide fumarate ("TAF"), penetrated target cells more efficiently than TDF and patients could receive the same benefits at a lower dose, which would in turn decrease toxicity. In an animal study published in 2001, Gilead found that TAF had 1,000-fold greater activity against HIV than TDF. In fact, a 25 mg dose of TAF achieves the same therapeutic effect as a 300 mg dose of TDF, with a better safety profile.

7. Despite TAF's clear superiority, Gilead's then-Chief Executive Officer John C. Martin announced in October 2004 that the corporation had stopped its TAF research. Based on an "internal business review," he said, Gilead's executives had concluded TAF was unlikely to be "highly differentiated" from TDF.

8. But Gilead did not actually abandon TAF. Instead, between October 2004 and May 2005, Gilead applied for at least seven patents associated with TAF. The company knew that by withholding the safer TAF design, it could extend the longevity of its increasingly profitable HIV drug franchise: first, with TDF medications until TDF patent expiration in 2018, and then with TAF medications until TAF patent expiration in 2032.

9. For Gilead, this scheme paid off in spades. The company's early TAF studies went unpublished for years, allowing TDF to become one of the world's most-prescribed drugs for HIV treatment. According to its 2017 10-K, Gilead's TDF-based product sales were $8.0 billion, $10.7 billion and $11.0 billion in 2017, 2016 and 2015, respectively, and accounted for 34%, 39% and 36% of Gilead's total antiretroviral product sales for those same years.

10. But for patients, Gilead's scheme was devastating. Gilead kept its TAF design on the shelf for over a decade, knowingly exposing patients taking its TDF-drugs to greater risks of kidney and bone toxicity. In a 2012 study, doctors at the University of California, San Francisco analyzed a

database of more than 10,000 HIV patients at the Department of Veterans Affairs, finding that the risk of chronic kidney disease rose by 33% each year that a patient took a TDF drug.

11. Aware that its TDF patent would expire in 2018, Gilead reported to investors in 2010 the discovery of "an interesting new molecule." But the molecule was not new; it was TAF. Gilead began publicly presenting results from pre-Viread TAF studies and, at a May 2011 medical conference, revealed the results of a 2003 patient trial showing that TAF was more effective than TDF at one-sixth of the dose.

12. Despite discovering and beginning pre-clinical testing of TAF before 2001, Gilead waited more than fourteen years, until November 5, 2014, to submit TAF for FDA approval. Gilead released its first TAF-containing product, Genvoya, in November 2015.

13. Gilead next convinced doctors to switch their patients from TDF-based to TAF-based regimens by demonstrating TAF's superior safety profile with respect to kidney and bone toxicity—the very benefits that Gilead could have and should have incorporated into its products since 2001. Today, Gilead's sales material reminds doctors of TDF's toxicity, and sales representatives urge them to prescribe its TAF-based regimens instead. To prove its case, Gilead's sales force is armed with head-to-head studies, each showing more signs of kidney and bone damage in patients taking TDF.

14. Gilead intentionally withheld a safer alternative design of TDF drugs it knew to be dangerously toxic to patients' kidneys and bones. Accordingly, Plaintiffs bring this action to recover damages for their personal injuries and seek punitive damages arising from Gilead's willful and wanton misconduct.

PARTIES

A. Plaintiffs

15. Plaintiffs are consumers who were prescribed and ingested Viread, Truvada, Atripla, Complera, and/or Stribild, and who suffered personal injuries as a result.

16. Plaintiff Charlene Alberty is a resident of the State of California. Ms. Alberty was prescribed and ingested Gilead's antiretroviral medication Atripla from approximately 2014 through the present. As a result of taking Atripla, Ms. Alberty developed and suffers from kidney failure, loss of bone minderal density, vitamin D deficiency, and Fanconi Syndrome. Ms. Alberty was unaware that her injuries were caused by Atripla until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of her injuries, she could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

17. Plaintiff Armando Arteaga is a resident of the State of Arkansas. Mr. Arteaga was prescribed and ingested Gilead's antiretroviral medications Viread and Truvada from approximately 2011 through 2018. As a result of taking Viread and/or Truvada, Mr. Arteaga developed and suffers from loss of bone mineral density, including but not limited to loss of numerous adult teeth, and vitamin D deficiency. Mr. Arteaga was unaware that his injuries were caused by Viread and/or Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

18. Plaintiff Deborah Ayala is a resident of the State of New York. Ms. Ayala was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately November 2013 through the present. As a result of taking Truvada, Ms. Ayala developed and suffers from bone breaks and fractures. Ms. Ayala was unaware that her injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

19. Plaintiff Justin Braly is a resident of the State of Texas. Mr. Braly was prescribed and ingested Gilead's antiretroviral medication Truvada for PrEP from approximately 2017 through 2018.

As a result of taking Truvada for PrEP, Mr. Braly developed and suffers from loss of bone mineral density. Mr. Braly was unaware that his injuries were caused by Truvada for PrEP until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

20. Plaintiff Jerry Brightman is a resident of the State of Texas. Mr. Brightman was prescribed and ingested Gilead's antiretroviral medication Atripla from approximately 2013 through March 2018. As a result of taking Atripla, Mr. Brightman developed and suffers from severe loss of bone mineral density, loss of multiple adult teeth, and vitamin D deficiency. Mr. Brightman was unaware that his injuries were caused by Atripla until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

21. Plaintiff Latifah Caesar is a resident of the State of New Jersey. Ms. Caesar was prescribed and ingested Gilead's antiretroviral medications Truvada and Stribld from approximately 2006 through 2016. As a result of taking Truvada and Stribld, Ms. Caesar developed and suffers from chronic kidney disease and loss of bone mineral density. Ms. Caesar was unaware that her injuries were caused by Truvada and Stribld until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of her injuries, she could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

22. Plaintiff Jose Carbajal Cruz is a resident of the State of Florida. Mr. Carbajal Cruz was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately 2013 through 2018. As a result of taking Truvada, Mr. Carbajal Cruz developed and suffers from loss of bone mineral density and vitamin D deficiency. Mr. Carbajal Cruz was unaware that his injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the

circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

23. Plaintiff Kenneth Fitz is a resident of the State of New York. Mr. Fitz was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately 2010 through 2018. As a result of taking Truvada, Mr. Fitz required a hip replacement at the young age of 45. Mr. Fitz was unaware that his injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

24. Plaintiff Alfredo Gallegos is a resident of the State of California. Mr. Gallegos was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately 2005 through 2018. As a result of taking Truvada, Mr. Gallegos developed and suffers from loss of bone mineral density, loss of multiple adult teeth, and vitamin D deficiency. Mr. Gallegos was unaware that his injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

25. Plaintiff Ramone Gary is a resident of the State of Pennsylvania. Mr. Gary was prescribed and ingested Gilead's prescription medication Stribld from 2012 through 2019. As a result of taking Truvada, Mr. Gary developed and suffers from loss of bone mineral density, loss of multiple adult teeth, and vitamin D deficiency. Mr. Gary was unaware that his injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

26. Plaintiff Pamela Glover is a resident of the District of Columbia. Ms. Glover was prescribed and ingested Gilead's antiretroviral medication Viread from approximately 2014 through

2018. As a result of taking Viread, Ms. Glover has suffered loss of bone mineral density, bone fractures, and bone breaks, all at the young age of 45. Ms. Glover was unaware that her injuries were caused by Viread until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, she could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

27. Plaintiff Javier Gomez is a resident of the State of California. Mr. Gomez was prescribed and ingested Gilead's antiretroviral medications Truvada and Atripla from 2007 through the present. As a result of taking Truvada and Atripla, Mr. Gomez developed and suffers from chronic kidney disease. Mr. Gomez was unaware that his injuries were caused by Truvada and Atripla until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

28. Plaintiff Johnny Green is a resident of the State of North Carolina. Mr. Green was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately 2016 through 2018. As a result of taking Truvada, Mr. Green developed and suffers from loss of bone mineral density, loss of multiple adult teeth, osteoporosis, and vitamin D deficiency. Mr. Green was unaware that his injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

29. Plaintiff Leon Green is a resident of the State of New York. Mr. Green was prescribed and ingested Gilead's prescription medication Atripla from approximately 2012 through the present. As a result of taking Atripla, Mr. Green suffers from chronic kidney disease. Mr. Green was unaware that his injuries were caused by Atripla until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have

reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

30. Plaintiff Dr. Phillip Greenberg is a resident of the State of Florida. Dr. Greenberg was prescribed and ingested Gilead's antiretroviral medication Viread from approximately 2002 through 2009. As a result of taking Viread, Dr. Greenberg developed and suffers from acute renal insufficiency and loss of bone mineral density resulting in a right fibular fracture. Dr. Greenberg was hospitalized for these injuries. Dr. Greenberg was unaware that his injuries were caused by Viread until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

31. Plaintiff Gregory Hart is a resident of the state of New Jersey. Mr. Hart was prescribed and ingested Gilead's antiretroviral medication Atripla from approximately June 2011 through September 2017. As a result of taking Atripla, Mr. Hart developed and suffers from chronic stage three kidney disease. Mr. Hart was unaware that his injuries were caused by Atripla until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the cause of action herein within the applicable statute of limitations period.

32. Plaintiff Tania Houston is a resident of the State of California. Ms. Houston was prescribed and ingested Gilead's antiretroviral medications Truvada and Atripla from approximately 2005 through the present. As a result of taking Truvada and Atripla, Ms. Houston developed and suffers from loss of bone mineral density and necrosis of the femoral head and hip socket. Ms. Houston has been recommended for a total hip replacement. Ms. Houston was unaware that her injuries were caused by Truvada and Atripla until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of her injuries, she could not have

reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

33. Plaintiff Jeral Hutchinson is a resident of the State of Mississippi. Mr. Hutchinson was prescribed and ingested Gilead's antiretroviral medication Complera from approximately 2013 through 2016. As a result of taking Complera Mr. Hutchinson developed and suffers from loss of bone mineral density. Mr. Hutchinson was unaware that his injuries were caused by Complera until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

34. Plaintiff Lisa Jackson-Gray is a resident of the State of Tennessee. Ms. Jackson-Gray was prescribed and ingested Gilead's antiretroviral medications Truvada and Complera from 2004 through approximately late 2018. As a result of taking Truvada and Complera, she developed and suffers from vitamin D deficiency and loss of bone mineral density. Ms. Jackson-Gray was unaware that her injuries were caused by Truvada and Complera until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of her injuries, she could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

35. Plaintiff Robert Jacobsen is a resident of the State of California. Mr. Jacobsen was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately September 2013 through June 2016. As a result of taking Truvada, Mr. Jacobsen suffered from severe loss of bone mineral density and was forced to have hip replacement surgery in 2017. Mr. Jacobsen was unaware that his injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

36. Plaintiff Theodus Kendrick is a resident of the State of Mississippi. Mr. Kendrick was prescribed and ingested Gilead's antiretroviral medication Atripla and another of Gilead's TDF-based antiretroviral medications from approximately 2001 through the present. As a result of taking Atripla, Mr. Kendrick developed and suffers from acute kidney injury and chronic kidney disease. Mr. Kendrick was unaware that his injuries were caused by Gilead's TDF-based medications until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

37. Plaintiff Charles Latham is a resident of the State of Oklahoma. Mr. Latham was prescribed and ingested Gilead's antiretroviral medications Truvada and Atripla from approximately 2005 through 2017. As a result of taking Truvada and Atripla, Mr. Latham developed severe loss of bone mineral density and at the young age of 36 was required to undergo hip replacement surgery. Mr. Latham was unaware that his injuries were caused by Truvada and Atripla until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

38. Plaintiff Leardis Leonard is a resident of the State of Georgia. Mr. Leonard was prescribed and ingested Gilead's antiretroviral medication Truvada and Atripla from approximately 2009 through the present. As a result of taking Truvada and Atripla, Mr. Leonard has developed and suffers from acute kidney injury and chronic kidney disease. Mr. Leonard was unaware that his injuries were caused by Truvada and Atripla until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

39. Plaintiff Kathey A. Macklberg, brings claims on behalf of her son, the deceased, Travis R. Reed. At all times relevant to this complaint, Mr. Reed was a resident of the State of Colorado. Mr. Reed was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately 2012 through 2017. As a result of taking Truvada, Mr. Reed developed acute kidney failure resulting in dialysis, hospitalization, and ultimately in the failure of his kidneys and his death on April 27, 2017, at the young age of 37. Mr. Reed had only been diagnosed with HIV in 2012, less than five years before his death was caused by ingestion of Truvada, which caused his kidneys to permanently shut down. Mr. Reed is survived by his mother, who brings these claims on his behalf and for her own, personal losses. Mr. Reed and Ms. Macklberg were unaware that Mr. Reed's injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, they could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

40. Plaintiff Mark Mallery is a resident of the State of California. Mr. Mallery was prescribed and ingested Gilead's antiretroviral medications Truvada and Atripla from approximately 2013 through 2017. As a result of taking Truvada and Atripla, Mr. Mallery developed and suffers from stage three chronic kidney disease. Mr. Mallery was unaware that his injuries were caused by Truvada and Atripla until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

41. Plaintiff Sheila Midget is a resident of the State of Maryland. Ms. Midget was prescribed and ingested Gilead's prescription medication Atripla from approximately 2007 through 2015. As a result of taking Atripla, Ms. Midget suffered severe bone mineral density loss, osteopenia, and premature bone fractures and breaks. Ms. Midget was unaware that her injuries were caused by Atripla until within two years of the filing of this complaint. Despite diligent investigation of the

circumstances of her injuries, she could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

42. Plaintiff Willie C. Morris is a resident of the State of Texas. Mr. Morris was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately 2010 through 2018. As a result of taking Truvada, Mr. Morris developed and suffers from chronic kidney disease, loss of bone mineral density, and bone necrosis. Mr. Morris was unaware that his injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

43. Plaintiff Jacquria Nelson is a resident of the State of Louisiana. Ms. Nelson was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately July 2013 through August 2018. As a result of taking Truvada, Ms. Nelson developed and suffers from vitamin D deficiency and loss of bone mineral density. Ms. Nelson was unaware that her injuries were caused by Truvada until within one year of the filing of this complaint. Despite diligent investigation of the circumstances of her injuries, she could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

44. Plaintiff Benjamin Patterson is a resident of the State of Georgia. Mr. Patterson was prescribed and ingested Gilead's antiretroviral medication Stribild from approximately 2013 through 2017. As a result of taking Stribild, Mr. Patterson developed and suffers from osteoporosis at the young age of 28. Mr. Patterson was unaware that his injuries were caused by Stribild until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

45. Plaintiff Sandra Polk is a resident of the State of Texas. Ms. Polk was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately 2001 through 2018. As a

result of taking Truvada, Ms. Polk developed and suffers from early onset, severe osteoporosis. Ms. Polk was unaware that her injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of her injuries, she could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

46. Plaintiff Robert Purell is a resident of the State of Georgia. Mr. Purell was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately 2001 through the present. As a result of taking Truvada, Mr. Purell developed and suffers from severe bone mineral density loss resulting in the loss of numerous adult teeth. Mr. Purell was unaware that his injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

47. Plaintiff Julie Reyes is a resident of the State of California. Ms. Reyes was prescribed and ingested Gilead's antiretroviral medications Atripla and Complera from approximately 2016 through the present. As a result of taking Atripla and Complera, Ms. Reyes developed and suffers from stage premature, severe loss of bone mineral density, bone breaks, and bone fractures at the young age of 37. Ms. Reyes was unaware that her injuries were caused by Atripla and Complera until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of her injuries, she could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

48. Plaintiff Nancy Rodriguez is a resident of the state of New York. Ms. Rodriguez Rodriguez was prescribed and ingested Gilead's antiretroviral medication Truvada from October 2007 until approximately the end of 2016. As a result of taking Truvada, Ms. Rodriguez developed and suffers from premature osteoporosis. Ms. Rodriguez was unaware that her injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of

the circumstances of her injuries, she could not have reasonably discovered facts supporting the cause of action herein within the applicable statute of limitations period.

49. Plaintiff Armando Sola is a resident of the State of Oregon. Mr. Sola was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately 2012 through 2018. As a result of taking Truvada, Mr. Sola developed and suffers from severe bone mineral density loss, necessitating a hip replacement at the young age of 43. Mr. Sola was unaware that his injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

50. Plaintiff Reuben Tucker is a resident of the State of California. Mr. Tucker was prescribed and ingested Gilead's antiretroviral medications Truvada, Complera, and Stribld from approximately 2010 through 2018. As a result of taking Truvada, Complera, and Stribld, Mr. Tucker developed and suffers from premature and severe loss of bone mineral density, bone breaks, and bone fractures. Doctors have recommended that Mr. Tucker endure a bilateral hip replacement. Mr. Tucker was unaware that his injuries were caused by Truvada, Complera, and Stribld until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

51. Plaintiff LaShawn Tynes is a resident of the State of Maryland. Mr. Tynes was prescribed and ingested Gilead's antiretroviral medication Truvada from approximately 2008 through the present. As a result of taking Truvada, Mr. Tynes suffered premature, severe bone mineral density loss, loss of multiple adult teeth, and premature bone breaks and fractures. Mr. Tynes was unaware that his injuries were caused by Truvada until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have

reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

52. Plaintiff David Williams is a resident of the State of Texas. Mr. Williams was prescribed and ingested Gilead's antiretroviral medication Stribld from approximately January 2018 through January 2019. As a result of taking Stribld, Mr. Williams developed and suffers from severe bone mineral density loss resulting in the loss of multiple adult teeth. Mr. Williams was unaware that his injuries were caused by Stribld until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

53. Plaintiff Bobby Williams is a resident of the State of Texas. Mr. Williams was prescribed and ingested Gilead's antiretroviral medications Truvada and Stribld from approximately October 2009 through 2016. As a result of taking Truvada and Stribild, Mr. Williams developed and suffers from chronic stage 4 kidney disease. Mr. Williams was unaware that his injuries were caused by Truvada and Stribild until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

54. Plaintiff James Woods is a resident of the State of California. Mr. Woods was prescribed and ingested Gilead's antiretroviral medications Atripla and Complera from approximately 2006 through 2014. As a result of taking Atripla and Complera, Mr. Woods developed and suffers from chronic stage 3 kidney disease. Mr. Woods was unaware that his injuries were caused by Atripla and Complera until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of his injuries, he could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

55. Plaintiff Arturo Zamora is a resident of the State of Kansas. Mr. Zamora was prescribed and ingested Gilead's prescription medications Truvada and Atripla from approximately

2013 through the present. As a result of taking Truvada and Atripla, and at the young age of 27, Mr. Zamora was diagnosed with and suffers from decreased kidney function, elevated creatinine levels, and premature, severe loss of bone mineral density. Mr. Zamora was unaware that his injuries were caused by Truvada and Atripla until within two years of the filing of this complaint. Despite diligent investigation of the circumstances of her injuries, she could not have reasonably discovered facts supporting the causes of action herein within the applicable statute of limitations period.

B. Defendant

56. Defendant Gilead Sciences, Inc. is a corporation organized under Delaware law with its principal office at 333 Lakeside Drive, Foster City, California 94404. Gilead is a multibillion-dollar pharmaceutical company that develops and commercializes prescription pharmaceuticals including Viread, Truvada, Atripla, Complera, and Stribild.

JURISDICTION AND VENUE

57. This Court has subject matter jurisdiction over all causes of action alleged in this Complaint pursuant to the California Constitution, Article VI, § 10, and is a Court of competent jurisdiction to grant the relief requested. Plaintiffs' claims arise under the laws of the State of California, are not preempted by federal law, do not challenge conduct within any federal agency's exclusive domain, and are not statutorily assigned to any other trial court.

58. This Court has personal jurisdiction over Gilead because the corporation is headquartered in San Mateo County and regularly conducts substantial business there.

59. Venue is proper in this Court pursuant to California Code of Civil Procedure sections 395 and 395.5 because Gilead is headquartered in San Mateo County and a substantial portion of Gilead's misconduct occurred in San Mateo County.

FACTUAL ALLEGATIONS

A. Gilead designed, manufactured, and marketed five TDF drugs.

60. Tenofovir was discovered in the 1980s by European scientists. Gilead, then a small biotech firm, bought the rights to sell it and, in 1997, worked with doctors from the University of California, San Francisco to show it fought HIV by blocking an enzyme the virus needs to replicate.

61. Tenofovir is a nucleotide analog reverse transcriptase and HBV polymerase inhibitor ("NRTI"). When tenofovir is absorbed into a cell and "activated" by the cell's biological machinery, it can prevent the process by which the HIV virus spreads.

62. The original formulation of tenofovir held little sales potential because it had to be given intravenously. To solve this problem, Gilead scientists modified the chemical composition to create a prodrug known as tenofovir disoproxil. The fumaric salt of tenofovir disoproxil is tenofovir disoproxil fumarate, commonly known as TDF. TDF held huge sales potential for Gilead because it could be taken orally.

63. Although TDF can be taken by mouth, the proportion of tenofovir that enters the cells is relatively low. In order to have the desired therapeutic effect, a patient must ingest a high dose of TDF: for adults, that does is 300 mg, every day.

64. Gilead has received FDA approval for five TDF-based drugs for the treatment of HIV.

TDF drug	**Active ingredients**	**FDA approval**
Viread	TDF 300 mg tablets	October 26, 2001
Truvada	TDF 300 mg/emtricitabine 200 mg tablets	August 2, 2004
Atripla	TDF 300 mg/emtricitabine 200 mg/efavirenz 600 mg tablets	July 12, 2006
Complera	TDF 300 mg/emtricitabine 200/rilpivirine 25 mg tablets	August 10, 2011
Stribild	TDF 300 mg/emtricitabine 200 mg/elvitegravir 150 mg/cobicistat 150 mg tablets	August 27, 2012

65. **Viread.** On October 26, 2001, the FDA approved Gilead's NDA 21356 for Viread (300 mg TDF) tablets for use in combination with other antiretroviral agents for the treatment of

HIV-1 infection. Gilead submitted limited clinical data supporting approval of the drug and had not completed Phase III clinical studies. Gilead 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). In 2008, the FDA approved an additional Viread indication for the treatment of Chronic Hepatitis B.

66. **Truvada.** On August 2, 2004, the FDA approved Gilead's NDA 21752 for Truvada tablets, which is a combination product containing 300 mg TDF (i.e., Viread) and 200 mg emtricitabine, for use in combination with other antiretroviral agents for the treatment of HIV infection in adults. 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. On July 16, 2012, the FDA approved an additional indication for the use of Truvada in combination with safer sex practices for pre-exposure prophylaxis (PrEP or Truvada for PrEP) to reduce the risk of sexually acquired HIV in adults at high risk.

67. **Atripla.** On July 12, 2006, the FDA approved Gilead's NDA 21937 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 antiretroviral agents for the treatment of HIV-1 infection in adults. Gilead submitted no clinical data in support of NDA 21937. 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.

68. **Complera.** On August 10, 2011, the FDA approved Gilead's NDA 202123 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-1 infection in treatment-naïve adults (i.e., 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 NDA 20123. Approval was based on the results of bioequivalence studies comparing the combination product to the individual component drugs.

69. **Stribild.** On August 27, 2012, the FDA approved Gilead's NDA 203100 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 of HIV-1 infection in treatment-naïve adults. Although elvitegravir and cobicistat had not been previously approved by the FDA, the FDA gave Gilead's Stribild NDA a 10-month standard review because there were already multiple regimens available for treatment naïve patients including one pill, once-a-day regimens.

B. Even before Viread was approved, Gilead knew that TDF posed a significant safety risk to patients' bones and kidneys.

70. Since scientists first synthesized TDF in 1997, studies have shown that it could cause significant kidney and bone damage, including decreases in bone mineral density, osteopenia, osteoporosis, Fanconi syndrome (renal tubular injury with severe hypophosphatemia), chronic kidney disease, and end stage kidney disease.

71. Even before Gilead's first TDF product, Viread, received FDA approval in 2001, Gilead knew that two of its other antiretroviral drugs—both structurally similar to tenofovir—caused significant kidney damage.

72. In December 1999, Gilead abandoned development of NRTI prodrug adefovir dipivoxil for the treatment of HIV after it proved toxic to patients' kidneys in the later stages of Phase III clinical trials. In Gilead's clinical trial of adefovir, 59% of patients demonstrated severe kidney toxicity after 72 weeks. One patient in the trial died due to multiorgan failure subsequent to kidney failure. Based on this experience, Gilead knew that adefovir dipivoxil was associated with delayed nephrotoxicity—meaning that its toxic effects might not be felt for some time after continued use.

73. Tenofovir, also an NRTI, has a nearly identical molecular structure to adefovir, varying only by the presence of one methyl group (i.e., a carbon atom bound to three hydrogen atoms) in

tenofovir, which replaces a hydrogen atom in adefovir. As a result, Gilead knew that the delayed nephrotoxicity issues it experienced with adefovir dipivoxil could also arise with TDF.

74. Gilead also knew that because TDF converts into free tenofovir outside of target cells, high levels of free tenofovir in the blood would be common and would endanger the kidneys and bones. Gilead's preclinical animal studies of TDF showed evidence of renal toxicity and bone toxicity in the form of softening of the bones (osteomalacia) and reduced bone mineral density. Nephrotoxicity in these animal studies was related to both dose and duration of therapy.

75. Finally, Gilead 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 more prevalent with long-term use of TDF, such use being an obvious need to combat a disease with no known cure.

C. With each passing year and each successive TDF product, Gilead learned – and ignored – even more about TDF's toxicity.

76. 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.

77. In the first two years Viread was on the market, 40% of Viread adverse events reports received by Gilead were related to the renal/urinary system. This included 49 cases of increased creatinine, 16 cases of hypophosphatemia, 42 cases of renal insufficiency, 51 cases of acute renal failure, 6 cases of chronic renal failure, and 32 cases of Fanconi syndrome. These numbers are likely far less than the true incidence of kidney damage experienced by Viread patients during this timeframe because postmarketing adverse events are underreported.

78. Viread's original prescribing information and patient information sheet said little about the severe risk of toxicity in kidneys and concomitant risk of bone mineral density loss. The boxed

warning for Viread has never mentioned TDF toxicity, bone, or kidney risks. And, the current label still only recommends assessment of bone mineral density for patients with a history of fracture or other risk factors for osteoporosis or bone loss.

79. 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.

80. As Gilead recognized in the Precautions section of the July 1, 2004 Viread label: "[h]igher tenofovir concentrations could potentiate Viread-associated adverse events, including renal disorders."[1]

81. As Gilead knew, these injuries were not limited to patients with a history of renal dysfunction or other risk factors. Instead, many of these injuries occurred in patients without preexisting kidney dysfunction.

82. According to a 2009 shareholder lawsuit filed against Viread, Viread's then-Chief Executive Officer John C. Martin frequently referred to Viread as a "miracle drug" at sales force meetings. According to a former employee, Gilead was trying to overcome the perception in the medical community that Viread was like Gilead's previous HIV drugs and would likely cause kidney damage.

[1] Viread (tenofovir disoproxil fumarate) Tablets label at 17, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21356slr010_viread_lbl.pdf.

83. On March 14, 2002, the FDA sent Gilead a Warning Letter admonishing Gilead for engaging in promotional activities that contained false and misleading statements in violation of the Federal Food, Drug and Cosmetic Act. The FDA stated that Gilead unlawfully minimized Viread's risks, including with respect to kidney toxicity, and overstated its efficacy.

84. Despite this warning, Gilead continued to unlawfully promote Viread by minimizing its safety risks. During a June 2003 sales force training, Gilead instructed sales representatives 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—some of them severe —including but not limited to renal failure, acute renal failure, Fanconi syndrome, proximal tubulopathy, increased creatinine, and acute tubular necrosis.

85. The FDA issued another Warning Letter to Viread on July 29, 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.

86. On March 26, 2010, the FDA issued another Warning Letter to Gilead, this time in connection with Gilead's direct-to-consumer print advertising for Truvada. The FDA warned that Gilead's Truvada advertisement was false and misleading because it overstated the efficacy of Truvada and minimized the risks associated with the drug, in violation of the Federal Food, Drug, and Cosmetic Act and FDA implementing regulations. The FDA noted that Truvada is associated with "serious risks" like new onset or worsening renal impairment, including cases of acute renal failure and Fanconi syndrome and decreases in bone mineral density, including cases of osteomalacia (associated with proximal renal tubulopathy and which may contribute to fractures). The agency stated that Gilead's Truvada advertising was false or misleading because it failed to present the risks associated with Truvada with a prominence and readability comparable to the statements regarding the drug's benefits.

87. In subsequent 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.

88. Gilead's long-term clinical data also demonstrated that TDF was damaging patients' bones. 48-week data showed greater decreases from baseline in bone mineral density at the lumbar spine and hip in patients taking Viread compared to those receiving other HIV drugs. At 144 weeks, there was a significantly greater decrease from baseline in bone mineral density at the lumbar spine in patients taking Viread compared to those receiving other HIV drugs, as well as significant increases in biochemical markers of bone turnover in patients taking Viread. Once Gilead began conducting clinical trials with Viread in adolescent and pediatric patients, the effects of TDF on adolescent and pediatric patients' bones were similar to the effects seen with adult patients.

89. After Gilead brought Truvada to market, the medical literature continued to identify cases of TDF-associated kidney damage, including in patients without pre-existing renal dysfunction or co-administration with another nephrotoxic drug.

90. Several new studies presented at the February 2006 Conference on Retroviruses and Opportunistic Infections ("CROI") highlighted the frequency of nephrotoxicity in TDF-treated patients. One study analyzed longitudinal data from 11,362 HIV-infected patients and found that treatment with TDF was significantly associated with mild and moderate renal insufficiency. Another observational study of 497 patients found that 17.5% developed renal dysfunction after initiating TDF treatment.

91. In 2007, Gilead published an article discussing the company's knowledge of TDF safety issues over the first four years of TDF treatment. Gilead reported that 0.5% of patients enrolled in a global expanded access program experienced a serious renal adverse event, including acute and

chronic renal failure and Fanconi syndrome. A "serious" adverse event meant one resulting in hospitalization or prolongation of hospitalization, death, disability, or requiring medical intervention to prevent permanent impairment. Gilead also reported that through April 2005 the most common serious adverse events reported to Gilead's postmarketing safety database were renal events, including renal failure, Fanconi syndrome, and serum creatinine increase.

92. 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. In its Medical Review of the Stribild NDA, the FDA noted the limitations of Gilead's data, including the short duration of treatment, the voluntary nature of adverse event reporting in some countries, and the fact that Gilead only assessed serious adverse events, and not renal events leading to drug discontinuation or non-serious renal adverse events. According to the FDA, any of these factors may have led to an underestimation of the true incidence of renal events of interest. The FDA similarly questioned Gilead's data on the incidence of renal adverse events based on its postmarketing safety database given the voluntary nature of reporting.

93. 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. In November 2008, Gilead modified the labeling to state that patients taking TDF had experienced osteomalacia due to proximal renal tubulopathy as bone pain, and that it might contribute to fractures.

94. In August 2008, Gilead had to update its labeling to recognize finally that TDF caused both "new onset" and "worsening" renal impairment—meaning, as Gilead knew years prior, that TDF was injuring patients' kidneys even though they had no preexisting renal dysfunction.

95. Studies from 2009 through 2011 continued to show that TDF caused a significant loss of renal function in HIV-infected patients.

96. Multiple articles described how the incidence of TDF-induced nephrotoxicity was underreported because studies often excluded patients who were likely to exhibit nephrotoxic effects,

including patients who combined TDF in a ritonavir-boosted regimen or with another nephrotoxic drug, older patients or those with advanced HIV disease, or those with mild baseline renal dysfunction. Notwithstanding selection bias that tended to hide TDF-associated kidney dysfunction, the evidence was clear that TDF caused renal tubular dysfunction in a significant percentage of HIV-infected patients.

97. In April 2012, researchers at the San Francisco Veterans' Administration Medical Center and the University of California, San Francisco published their analysis of the medical records of more than 10,000 HIV-positive veterans in the national VA healthcare system, which is the largest provider of HIV care in the United States. The researchers found that for each year of tenofovir exposure, risk of protein in urine—a marker of kidney damage—rose 34%, risk of rapid decline in kidney function rose 11%, and risk of developing chronic kidney disease rose 33%. The risks remained after the researchers controlled for other kidney disease risk factors such as age, race, diabetes, hypertension, smoking, and HIV-related factors.

98. By the time it reviewed the Stribild NDA, the FDA stated that the safety profile of TDF was, by that point, "well-characterized in multiple previous clinical trials and is notable for TDF-associated renal toxicity related to proximal renal tubule dysfunction and bone toxicity related to loss of bone mineral density and evidence of increased bone turnover."

99. 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 TAF.

D. Gilead knew about TAF, a safer alternative to TDF, before Viread was approved for sale in 2001.

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

101. 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. TAF differs from TDF in its penetration into target cells. Unlike TDF, which is converted into the parent drug tenofovir in the gastrointestinal tract, liver, and blood, TAF is not converted into tenofovir until it has been absorbed by the cell. This allows TAF to be more efficiently absorbed by "target cells"—i.e., cells that HIV infects or "targets"—compared to TDF.

102. This more efficient absorption allows TAF to achieve far greater intracellular concentrations of the activated drug (tenofovir-diphosphate) in target cells than even a dramatically larger dose of TDF. This enhanced efficiency in absorption leads to plasma concentrations of tenofovir that are 90% lower than TDF, while still maintaining intracellular concentrations of activated drug in target cells that is the same or higher than TDF. The lowered plasma concentrations of tenofovir found with TAF result in reduced toxicity compared to TDF, making TAF safer to use than TDF.

103. On July 21, 2000, Gilead filed a provisional patent application which described TAF (then called GS-7340) as two to three times more potent than TDF while providing 10 times the intracellular concentration of tenofovir than TDF. 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. Gilead's preclinical studies of TAF also indicated that TAF is less likely to accumulate in renal proximal tubules than TDF, supporting the potential for an improved renal safety profile.

104. In April 2001, Gilead scientists published "Metabolism of GS-7430, A Novel Phenyl Monophosphoramidate Intracellular Prodrug of PMPA, In Blood," which compared the distribution of the active drug tenofovir in blood cells and plasma after exposure to either GS-7430 or tenofovir disoproxil (which was still in clinical development at the time of the study). Gilead found that a patient

need only 1/1000 of the dose of GS-7340 compared to tenofovir to achieve the same level of inhibition of HIV replication in vitro. Gilead also found that one need to use only one tenth the dose of GS-7340 compared to TDF to reach the same levels of active tenofovir inside cells.

105. Gilead researchers presented the results of its GS-7340 study at a February 2002 Conference on Retroviruses. John Milligan, then Gilead's Vice President of Corporate Development and current President and Chief Executive Officer, said that Gilead's goal with GS-7340 was to deliver a more potent version of tenofovir that can be taken in lower doses, resulting in better antiretroviral activity and fewer side effects. Milligan said that "there's a great need to improve therapy for HIV patients."[2]

106. Gilead's 2001 10-K highlighted the benefits of GS-7340 over Viread:

> Both GS 7340 and Viread are processed in the body to yield the same active chemical, tenofovir, within cells. However, the chemical composition of GS 7340 may allow it to cross cell membranes more easily than Viread, so that with GS 7340, tenofovir may be present at much higher levels within cells. As a result, GS 7340 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."[3]

107. In December 2003, Mark Perry, then Gilead's Executive Vice President of Operations, told investors that Gilead was "excited" about GS-7340. Gilead expected GS-7340 to achieve "more potency at lower doses and increase the therapeutic index for" tenofovir.[4] The "therapeutic index" is a comparison of the amount of a therapeutic agent that causes the therapeutic effect compared to the amount that causes toxicity.

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2 Special Coverage: 9th Conference on Retroviruses – New drugs, new data hold promise for next decade of HIV treatment, AIDS Alert, May 1, 2002.

3 Gilead Sciences, Inc. Form 10-K For the fiscal year ended December 31, 2001 at 13, available at https://www.sec.gov/Archives/edgar/data/882095/000091205702011690/a2073842z10-k.htm.

4 Gilead Sciences at Harris Nesbitt Gerard Healthcare Conference 2003 – Final, FD (Fair Disclosure) Wire, Dec. 11, 2003.

108. At a May 2004 Deutsche Bank Securities Healthcare Conference, Gilead said that it knew GS-7340 could be dosed at a fraction of the Viread dose and give a greater antiretroviral response.

E. Gilead withheld its safer TAF design to protect TDF sales and extend profits on its HIV franchise.

109. On October 21, 2004, shortly after the FDA approved Truvada, the first of four patent-extending combination antiretroviral pills, Gilead abruptly announced it would abandon its safer GS-7340 design. It stated:

> Earlier this year as a result of positive data from a small phase I/II study of GS 7340, we began designing a phase II program to determine the safety and efficacy of the compound in treatment-naive patients and in highly treatment experienced patients. Since that time we 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 GS 7340, we came to the conclusion that it would be unlikely that GS 7340 would emerge as a product that could be highly differentiated from Viread.[5]

110. Gilead's "internal business review" was the real driver of its decision to abandon a design it knew to be safer than Viread.

111. Gilead shelved its TAF design because it did not want to hurt TDF sales by admitting that TDF is unreasonably and unnecessarily unsafe.

112. In May 2005, despite Gilead's misrepresentation that GS-7340 was not worth pursuing, Gilead scientists reported the favorable results they achieved with GS-7340, including its benefits over Viread, in an issue of Antimicrobial Agents and Chemotherapy. Reuters Health News reported:

> After oral administration of GS 7340 to dogs, tenofovir concentrations were 5- to 15-fold higher in lymph nodes than after tenofovir DF administration, the researchers note. Except for kidney and liver, tissue concentrations of tenofovir were generally higher after GS 7340 than after tenofovir DF administration.
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> "The high concentrations of tenofovir observed in lymphatic tissues after oral administration of GS 7340 are expected to result in increased clinical potency relative

5 https://www.gilead.com/news/press-releases/2004/10/gilead-discontinues-development-of-gs-9005-and-gs-7340-company-continues-commitment-to-research-efforts-in-hiv.

> to tenofovir DF and could have a profound effect on the low-level virus replication that occurs in tissues with suboptimal drug exposure during HAART," the authors conclude.
>
> "With GS 7340," the researchers add, "it should be possible to reduce the total dose of tenofovir, thereby minimizing systemic exposure, while at the same time increasing antiretroviral activity."[6]

113. Gilead filed seven applications for patents on TAF between 2004 and 2005.

114. Despite recognizing the safety benefits of TAF, Gilead kept its GS-7340 design on the shelf for years, knowingly exposing patients taking its TDF-containing drug products to greater risks of kidney and bone toxicity. Gilead created TAF-based versions of its TDF drugs only after the corporation realized billions in sales through most of the TDF patent life.

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

116. Once Gilead renewed development of its TAF design, it again touted the benefits of TAF over TDF, as though it had never falsely claimed that TAF could not be "highly differentiated" from TDF. Milligan told investment analysts in 2010 that the safer TAF-designed products could replace the whole TDF franchise which would provide a "great deal of longevity. . . ."[7] Milligan similarly told investors at a Deutsche Bank Securities Inc. Healthcare Conference in May 2011 that TAF was a "new" drug that "could potentially bring quite a bit of longevity to the Gilead portfolio."[8]

117. As Milligan told analysts at a Goldman Sachs Global Healthcare Conference in June 2011, Gilead would be "offering a product called 7340, which we believe is a lower dose, better safety

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6 Novel tenofovir prodrug preferentially targets lymphatic tissue, Reuters Health Medical News, June 1, 2005.

7 Gilead Sciences at 22nd Annual Piper Jaffray Healthcare Conference – Final, FD (Fair Disclosure) Wire, Nov. 30, 2010.

8 Gilead Sciences Inc. at Deutsche Bank Securities Inc. Health Care Conference – Final, FD (Fair Disclosure) Wire, May 3, 2011.

profile, more potent, differentiated drug relative to Viread. And so, our ability to develop and get that onto the market prior to [TDF] patent expiration will be key to us, to maintain the longevity"[9]

118. On October 31, 2012, Gilead announced that a Phase II clinical trial evaluating TAF met its primary objective. The study compared a once-daily single tablet regimen containing TAF 10 mg/elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg with Stribild (TDF 300 mg/elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg) among treatment-naïve adults. Compared to Stribild, the TAF-containing regimen demonstrated better markers of bone and kidney effects that were statistically significant. The study showed that TAF is effective at a fraction of the dose of Viread and provides safety advantages.

119. In January 2013, Gilead began Phase III clinical development of TAF. Announcing the beginning of Phase III development, then-CEO Martin mischaracterized TAF as "new."[10]

120. Gilead finally submitted an application to market its first TAF-containing product, Genvoya, to the FDA on November 5, 2014 (an application it could have filed years earlier had it not shelved the safer design to make more money). By delaying the filing of an NDA for its first TAF product, for which it received five-year regulatory exclusivity, 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 even file an ANDA with a Paragraph IV certification seeking 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.

121. On November 5, 2015, the FDA approved Gilead's NDA 207561 for Genvoya tablets, a fixed dose combination product which contains 10 mg TAF, 200 mg emtricitabine, 150 mg

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9 Gilead Sciences Inc. at Goldman Sachs Global Healthcare Conference – Final, FD (Fair Disclosure) Wire, June 7, 2011.

10 Gilead Sciences at JPMorgan Global Healthcare Conference – Final, FD (Fair Disclosure) Wire, Jan. 7, 2013.

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.

122. In seeking FDA approval of Genvoya in 2014, Gilead relied on TAF data obtained by Gilead more than a decade earlier—before the company abruptly shelved its TAF design in pursuit of more money. Gilead submitted data from: (a) early clinical development showing that TAF provided greater intracellular distribution of tenofovir yielding lower plasma tenofovir levels than TDF; (b) preclinical studies that indicated TAF is less likely to accumulate in renal proximal tubules, supporting the potential for an improved renal safety profile; and (c) Phase I dosing studies supporting doses of TAF far lower than the standard 300 mg dose of TDF.

123. When the FDA approved Genvoya, John C. Martin, then Chairman and CEO of Gilead, announced that "there is still a need for new treatment options that may help improve the health of people as they grow older with the disease."[11] Martin misrepresented that TAF was "new" and concealed that Gilead had known about this safer version of tenofovir for over a decade but purposefully withheld it from the market solely to protect its monopoly profits and extend Gilead's ability to profit on TAF regimens for the next decade or more.

124. Gilead's TAF-based product websites, including the Genvoya site, market the TAF-based drugs as superior to Gilead's TDF-containing products with respect to kidney health. Gilead recognizes that: "Kidneys play a key role in keeping you healthy, working around the clock to remove waste from your blood. That's why it's so important to take care of them, especially if you have HIV-1."[12] Gilead states that the TAF-based products have "less impact on kidney lab tests" than other approved HIV-1 treatments, including Stribild, Atripla, and Truvada. The website also highlights that unlike its TDF products, the TAF-based products are "FDA-approved for people with mild-to-

11 US FDA approvals Gilead's Single Table Regiment Genvoya for Treatment of HIV-1 Infection, Business Wire, Nov. 5, 2015.

12 See https://www.genvoya.com/hiv-kidney-bone-health.

moderate kidney problems and can be used in some people with lowered kidney function without changing the dose."[13]

125. The Genvoya site also touts clinical studies which demonstrate that the TAF-containing products "had less impact on hip and lower spine bone mineral density than the other approved HIV-1 treatments," including Stribild, Atripla, and Truvada.[14]

126. According to Milligan, Genvoya was the most successful launch ever for an HIV therapy. After six months on the market, Genvoya was the most prescribed regimen for treatment-naïve (i.e., adults who had not been previously treated for HIV) and switch patients.

127. Gilead's conversion strategy continued with FDA approval of Gilead's subsequent TAF-based products, Odefsey and Descovy. As Milligan stated in March 2016, the marketplace was moving to TAF because patients need the safest possible medication:

> [A]s I look at TAF right now there's a very strong medical rationale for TAF versus Viread. And so what we're seeing in the marketplace with the launch of Genvoya and then with the recent approval of Odefsey is the desire to move patients from a TDF containing regimen to a TAF containing regimen. . . it's very interesting that the field wants to move to the safest medication, I think should move to the safest medication because it's a great opportunity for patients to stay on care for another 10 to 20 years which is really where we're at with most of these patients. They're going to need decades more care and so you need the gentlest, safest option for patients. . . .[15]

128. On March 1, 2016, the FDA approved Gilead's NDA 208351 for Odefsey tablets, which is a combination product 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.

129. On April 4, 2016, the FDA approved Gilead's NDA 208215 for Descovy tablets, which is a fixed dose combination product containing 25 mg TAF and 200 mg emtricitabine. The

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13 Id.

14 Id.

15 Gilead Sciences Inc. at Barclays Global Healthcare Conference – Final, FD (Fair Disclosure_ Wire, Mar. 15, 2016.

TDF-based counterpart to Descovy is Truvada. Descovy is identical to Truvada except for the substitution of TAF for TDF.

TAF drug	TDF counterpart	Active ingredients	FDA approval
Descovy	Truvada	TAF 25 mg/emtricitabine 200 mg tablets	April 4, 2016
Odefsey	Complera	TAF 25 mg/emtricitabine 200/rilpivirine 25 mg tablets	March 1, 2016,
Genvoya	Stribild	TAF 10 mg/emtricitabine 200 mg/elvitegravir 150 mg/cobicistat 150 mg	November 5, 2015

130. 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 those labels. Bone toxicity remains in the Warnings and Precautions sections of the labels of Gilead's TDF drugs to this day.

131. In January 2018, Milligan stated that "physicians and patients prefer TAF dramatically over our TDF-containing backbones," noting that its TAF-based products had achieved more than 56% of the market share of its TDF-containing regimen. TAF-based products now make up at least 74% of Gilead's TDF- and TAF-based drug products for HIV treatment.

132. Gilead could have and should have incorporated the benefits of TAF, which doctors and patients "prefer dramatically" over TDF, into its products years earlier. Gilead withheld its safer TAF design until it suited Gilead's bottom line, at the expense of patients' health.

F. Gilead knowingly designed its TDF drugs to be unreasonably dangerous and unsafe to patients' kidneys and bones.

133. Despite knowing that TDF causes kidney and bone damage and that TAF is safer for patients' kidneys and bones, Gilead designed the TDF Drugs to contain TDF rather than safer TAF.

134. In addition to withholding the safer TAF design of Stribild, Gilead made Stribild even more dangerous to patients when it formulated the drug to include 300 mg TDF in a fixed dose combination with cobicistat. Gilead knew before Viread entered the market in 2001 that combining TDF with cobicistat would significantly increase tenofovir levels in patients' blood. In fact, Gilead's

Stribild clinical trials showed an increased rate of serious renal adverse events that led to treatment discontinuation. But Gilead did not reduce the dose of TDF when it formulated Stribild.

135. When Gilead formulated its first TAF-based drug, Genvoya—which was Stribild with TAF in place of TDF—Gilead reduced the dose of TAF to account for the fact that cobicistat increases tenofovir concentrations. A Phase I TAF dosing trial showed that TAF 25 mg was the optimal dose to achieve activity similar to a 300 mg dose of TDF. When formulating Genvoya, however, Gilead further reduced the TAF dose to 10 mg because, when given with cobicistat, TAF 10 mg achieves exposure similar to TAF 25 mg when given without cobicistat.

136. Gilead knew to reduce the dose of TAF to 10 mg when given with cobicistat even before Gilead sought FDA approval for Stribild. In its Phase I study GS-US-311-0101, conducted between June 6, 2011 and August 31, 2011, Gilead determined that co-administration of TAF with cobicistat significantly increased the body's exposure to TAF and active tenofovir.[16] As a result, Gilead reduced the TAF dose when formulating Genvoya even though patients' plasma exposure to tenofovir when taking TAF is already significantly less than their tenofovir exposure when taking TDF due to TAF's enhanced entry and absorption into target cells.

137. In July 2011, months before Gilead submitted its Stribild NDA to the FDA, Gilead sought FDA approval of reduced doses of TDF (Viread) in 150 mg, 200 mg, and 250 mg strengths for the treatment of HIV-1 infection in pediatric patients ages 2-12. That same month, Gilead also sought approval of Viread 40 mg oral powder for the treatment of HIV-1 infection in pediatric patients 2 years and older.[17] The FDA approved the lower dosage strength TDF tablets and oral powder in early January 2012—over six months before the FDA approved the Stribild NDA. There

16 FDA Center for Drug Evaluation and Research, Genvoya NDA 207561 Clinical Pharmacology and Biopharmaceutics Review(s) at 32, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/207561Orig1s000ClinPharmR.pdf.

17 In the EU, Gilead recommends that adults with creatinine clearance below 50 mL/min take Viread oral powder to reduce their doses of TDF.

was no reason Gilead could not have similarly reduced the dose of TDF in Stribild, when it knew that failing to reduce the dose would increase the drug's toxicity.

138. As a direct result of Gilead's decision not to use a safer design, Stribild proved to be toxic to patients' kidneys and bones. In the clinical trials of Stribild over 48 weeks, eight patients in the Stribild group compared to one in the comparator groups discontinued the drug study due to renal adverse events, including kidney failure and Fanconi Syndrome. Four of these patients developed laboratory findings consistent with proximal renal tubular dysfunction. The laboratory findings in these four subjects improved but did not completely resolve upon discontinuation of Stribild. The signature toxicity of the Stribild group was proximal renal tubular dysfunction.

139. According to the FDA, the "most important safety risks of Stribild use are associated with two key toxicities: renal adverse events (particularly proximal renal tubular dysfunction) and bone toxicity. Both of these events have previously been associated with use of TDF . . . ."[18]

140. Due to Stribild's renal toxicity, Stribild use is restricted in patients with impaired renal function. Stribild's label states that doctors should not initiate Stribild in patients with estimated creatinine clearance below 70 mL per minute, and Stribild should be discontinued if estimated creatinine clearance declines below 50 mL per minute as dose interval adjustment cannot be achieved. Moreover, in the EU—though not in the U.S.—Gilead warns doctors that Stribild should not be initiated in patients with creatinine clearance below 90 mL per minute unless, after review of all available treatment options, it is considered that Stribild is the preferred treatment for the individual patient.

141. Gilead's post-approval Stribild data continued to show renal adverse effects. In the clinical trials of Stribild over 96 weeks, two additional Stribild patients discontinued the study due to a renal adverse reaction. In the clinical trials of Stribild over 144 weeks, three additional Stribild

18 FDA Center for Drug Evaluation and Research Stribild NDA 203100 Cross Discipline Team Member Review at 17, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/203100Orig1s000CrossR.pdf.

patients discontinued the study due to a renal adverse reaction. In addition, one patient who received ritonavir-boosted atazanavir plus Truvada (i.e., a boosted TDF regimen) in the comparator group developed laboratory findings consistent with proximal renal tubular dysfunction leading to drug discontinuation after week 96.

TOLLING OF THE STATUTE OF LIMITATIONS

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

143. 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.

144. Gilead concealed that it shelved 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.

145. Gilead misrepresented that it renewed development of TAF because of the needs of an aging HIV population. Gilead knew by 2004 when it halted TAF development that, as a result of highly active antiretroviral therapy ("HAART"), many HIV patients had a normal life expectancy.

146. For years, Gilead publicized the pretext for its decision to halt and then renew TAF development in order to conceal the existence of Plaintiffs' claims.

147. Gilead concealed that it did not reduce the dose of TDF in Stribild even though it knew to reduce the tenofovir prodrug dose when combined with cobicistat.

148. 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.

149. Because of Gilead's misrepresentations and omissions, Plaintiffs did not know and had no reason to suspect that Gilead's wrongdoing was the cause of their injuries and could not have discovered their claims within two years of filing their complaint.

150. 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.

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

152. Because of Gilead's misrepresentations and omissions, neither Plaintiffs nor any reasonable person would have had reason to conduct an investigation. Once Plaintiffs suspected that Gilead's wrongdoing was the cause of their injuries, they were diligent in trying to uncover the facts.

153. Gilead's misrepresentations and omissions regarding its refusal to earlier market TAF-designed products and the true risks of TDF constitute continuing wrongs that continue to this day.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
Strict Products Liability – Design Defect

154. Plaintiffs reallege and incorporate by reference herein all allegations above.

155. Gilead designed, developed, manufactured, fabricated, tested or failed to test, inspected or failed to inspect, labeled, advertised, promoted, marketed, supplied, and distributed the prescription drugs Viread, Truvada, Atripla, Complera and Stribild.

156. Gilead designed each of these drugs to contain TDF as the prodrug formulation of tenofovir before Gilead submitted any applications for these drugs to the FDA for approval.

157. Gilead chose to design its TDF drugs with the TDF prodrug formulation in order to maximize profits on sales of TDF.

158. Gilead delayed releasing TAF prodrug formulations of until at the earliest, late 2014. Gilead delayed the release of this safer and more effective formulation in order to maximize profits on sales of TDF and later on sales of TAF.

159. The TDF drugs manufactured and supplied by Gilead were defective and unsafe for their intended purpose because the ingestion of the TDF drugs causes serious injuries and/or death. The defects existed in the TDF drugs at the time they left Gilead's possession.

160. The TDF drugs did, in fact, cause personal injuries as described above while being used in a reasonably foreseeable manner, thereby rendering the TDF drugs defective, unsafe, and dangerous for use.

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

162. The TDF drugs were defective and unreasonably dangerous because their design included TDF and presented excessive danger that was preventable by designing the drugs to use the TAF prodrug formulation. Gilead knew that TAF was a safer and more effective design for delivering the drug tenofovir to the body and further knew TAF was capable of reducing the risk of bone and kidney damage to patients that occurred with using TDF as a design for delivering tenofovir to the body.

163. Gilead knew and intended that its TDF drugs would be used by the ordinary purchaser or user without inspection for defects therein and without knowledge of the hazards involved in such use.

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

165. At all times relevant to this matter, Gilead was aware that members of the general public who would ingest their product, including Plaintiffs, had no knowledge or information indicating that use of their product could cause the alleged injuries, and Gilead further knew that members of the general public who used their product, including Plaintiffs, would assume, and in

fact did assume, that said use was safe, when in fact said use was extremely hazardous to health and human life.

166. With this knowledge, Gilead opted to manufacture, design, label, distribute, offer for sale, supply, sell, package, and advertise its TDF drugs without attempting to protect TDF drug users from the high risk of injury or death resulting from TDF drug use.

167. Rather than attempting to protect users from the high risk of injury or death resulting from use of its product, Gilead intentionally failed to reveal its knowledge of the risks and consciously and actively concealed and suppressed said knowledge from members of the general public, including Plaintiffs, thus impliedly representing to members of the general public that its TDF drugs were safe for all reasonably foreseeable uses.

168. Gilead was motivated by their own financial interest in the continuing uninterrupted manufacture, supply, sale, marketing, packaging and advertising of its TDF drugs.

169. In pursuit of this financial motivation, Gilead consciously disregarded the safety of product users and in fact were consciously willing and intended to permit its TDF drugs to cause injury to users and induced persons, including Plaintiffs, to purchase and use those drugs.

170. As a proximate and legal result of the defective and unreasonably dangerous condition of the TDF drugs that Gilead designed, tested, manufactured and supplied, Plaintiffs were caused to suffer the injury and damages.

171. Gilead, their "alternate entities," and their officers, directors and managing agents participated in, authorized, expressly and impliedly ratified, and had full knowledge of, or should have known, each of the acts set forth herein.

172. Gilead's conduct was and is willful, malicious, fraudulent, outrageous and in conscious disregard of and indifference to the safety and health of the users of their product. Plaintiffs, for the sake of example and by way of punishing said Gilead, seek punitive damages according to proof.

SECOND CAUSE OF ACTION
Negligence

173. Plaintiffs reallege and incorporate by reference herein all allegations above.

174. Gilead had a duty to exercise reasonable care in the design, manufacture, sale, and/or distribution of Viread, Truvada, Atripla, Complera and Stribild into the stream of commerce, including a duty to assure that the products did not cause users to suffer from unreasonable, dangerous side effects.

175. By the manner in which it undertook to exclusively design, manufacture, promote and distribute tenofovir-based antiretroviral medications for the HIV/AIDS community – to the legal exclusion of all others – Gilead voluntarily assumed and/or undertook a legal and factual duty to exercise reasonable care and to comply with the standard of care in the design, manufacture, marketing and sale of its pharmaceutical products.

176. Gilead's duties included:

a. The duty to refrain from selling unreasonably dangerous products;

b. The duty to ensure its pharmaceutical products do not cause patients to suffer from foreseeable risks of harm;

c. The duty to design Viread, Truvada, Atripla, Complera, and Stribild with TAF, a known, safer alternative to TDF;

d. The duty to monitor the adverse effects associated with its pharmaceutical products, including its TDF drugs;

e. The duty to warn of the adverse effects associated with its pharmaceutical products, including its TDF drugs, to avoid reasonably foreseeable risks of harm to patients;

f. The duty to fully inform patients and physicians of any laboratory tests necessary and/or helpful in identifying adverse reactions to its pharmaceutical products, including the TDF drugs, and recommend the frequency with which such tests should be performed; and

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

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

178. Gilead knew that its TDF drugs were associated with elevated risks of kidney and bone toxicity and caused injuries that resulted from kidney and bone toxicity, including in patients not otherwise at risk for such injuries.

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

180. Gilead willfully and deliberately failed to avoid those consequences, and in doing so, Gilead acted with a conscious disregard of Plaintiffs' safety.

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

182. Despite the fact that Gilead knew or should have known that its TDF drugs caused unreasonable and dangerous side effects, Gilead continued to market its TDF drugs to consumers, including Plaintiffs.

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

184. Gilead undertook to develop and market safe antiretroviral medications to sell to wholesalers and other direct purchasers of pharmaceuticals, recognizing that its development and

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

185. Gilead failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of its TDF drugs into interstate commerce in that Gilead knew or should have known that its TDF drugs created a high risk of unreasonable, dangerous side effects.

186. Gilead could and should have sought FDA approval its TAF drugs earlier than 2014, when it sought FDA approval of Genvoya based on TAF data obtained by Gilead more than a decade earlier.

187. Gilead was negligent in the design, manufacture, testing, advertising, marketing and sale of its TDF drugs.

188. 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, especially when compared to the more effective and safer TAF.

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

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

THIRD CAUSE OF ACTION
Fraud and Concealment

191. Plaintiffs reallege and incorporate by reference herein all allegations above.

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

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

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

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

196. As described *supra*, Gilead concealed material facts concerning its TDF drugs from Plaintiffs, their physicians, and other healthcare providers. Specifically, Gilead actively concealed:

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

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

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

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

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

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

199. Gilead intentionally, willfully, and maliciously concealed and/or suppressed material information from prescriber and patient labeling regarding the need for doctors to monitor all TDF

patients on a frequent, specific schedule, for the adverse effects of TDF-associated bone and kidney toxicity.

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

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

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

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

204. Plaintiffs do not allege that Gilead's fraudulent statements or misrepresentations to the FDA were the cause of their injuries.

205. Had Gilead not intentionally, willfully and maliciously concealed and/or suppressed this information about the safe use of its TDF 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 Plaintiffs.

206. If Plaintiffs had been adequately monitored for kidney and bone problems while taking Gilead's TDF drugs, they would not have been injured or their injuries would have been less severe.

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

208. Gilead actively concealed these material facts by, inter alia, misrepresenting: (a) that any tenofovir-induced toxicity was rare and unavoidable; (b) why Gilead had purportedly abandoned

development of TAF in 2004; and (c) that TAF was "new" once Gilead finally introduced the safer TAF-based medications over a decade later.

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment in their favor and for against Defendant Gilead Sciences, Inc. as follows:

A. Declare, adjudge, and decree the conduct of Gilead as alleged herein to be unlawful, unfair, and/or deceptive and otherwise in violation of the law;

B. Award Plaintiffs actual, compensatory, and/or statutory damages in an amount to be proven at trial;

C. Award Plaintiffs punitive and exemplary damages as permitted by law and the statutes cited herein in an amount to be proven at trial;

D. Award Plaintiffs 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. Award Plaintiffs the costs of bringing this suit, including reasonable attorneys' fees; and

F. Award Plaintiffs any other further legal and equitable relief to which Plaintiffs may be entitled.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury of all claims and causes of action so triable in this lawsuit.

DATED: May 16, 2019

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