UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

CHRISTOPHER PIEROT, Plaintiff v. GILEAD SCIENCES, INC. Defendant.	CASE NO.: _____ COMPLAINT AND DEMAND FOR JURY TRIAL

COMPLAINT FOR DAMAGES

1. Plaintiff, Mr. Christopher Pierot, brings this personal injury action against Defendant Gilead Sciences, Inc. ("Gilead") to recover monetary damages and other remedies for violations of Louisiana law.

STATEMENT OF THE CASE

2. Plaintiff Christopher Pierot was diagnosed with HIV in 2008. He began treatment almost immediately and was prescribed the antiretroviral medication, Truvada. Like most antiretroviral medications, Truvada works to prevent the human immunodeficiency virus (HIV) from replicating within the body. Preventing replication of the virus helps reduce transmission rates and benefits the patient's immune system. Truvada was one of seven antiretroviral medications in its class, called nucleoside reverse transcriptase inhibitors (NRTIs), available to Mr. Pierot and his doctor in 2008.

3. Mr. Pierot took Truvada to treat and manage his HIV through late 2009. He took the pill daily, as prescribed, and trusted it would protect his health and keep his viral load low.

4. Unfortunately, and unknown to Mr. Pierot or his medical providers, the Truvada

have kept his viral load manageable, but did so at great cost to his bones and bone mineral density.

5. Truvada's developer and manufacturer, Gilead, had long known that Truvada, suffered from low bioavailability[1] and had to be ingested at high doses in order to provide the promised antiviral effect.

6. Truvada's low bioavailability and high dosage meant that Mr. Pierot's body, already tasked with fighting HIV infection, would be required to process through large amounts of the drug before it could reach the needed concentration level of tenofovir (the drug's active compound) in Mr. Pierot's blood and plasma sufficient to prevent the virus from replicating.

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

8. Gilead knew of Truvada's shortcomings from the very beginning of its development. Its low bioavailability was known, and preclinical toxicity studies showed kidneys and bones to be the target organs for toxicity when high doses of Truvada were administered.

9. And yet, with full knowledge of Truvada's toxicity, Gilead failed to adequately warn Mr. Pierot or his doctors of his risk for bone mineral density loss, bone necrosis, and/or bone fracture. Gilead's label downplayed the toxicity studies and suggested only that doctors "consider monitoring" bone mineral density "in patients with a history of pathologic fracture or

[1] Bioavailability is the amount of a drug that enters circulation when introduced to the body. It is essentially a measure of absorption.

who are at risk for opsteopenia.

10. Only 26 years old at the time he began taking Truvada, Mr. Pierot had no history of fractures and was not at risk for osteopenia.

11. Had Mr. Pierot's doctors known that Truvada presented a risk bone mineral density loss, bone necrosis, and/or bone fracture for patients without any related history, they could have chosen another NRTI in 2008, switched Mr. Pierot's medication along the way, or monitored his bone mineral density more closely.

12. Gilead not only knew and failed to adequately warn of Truvada's risks to Mr. Pierot's bones, it also intentionally withheld a safer and more effective design of the drug in order to maximize monopoly profits.

13. Long before Gilead developed Truvada, Gilead had discovered and tested a similar form of the drug that could be given in lower doses with reduced toxicity to kidneys and bones. But, an improved form of the drug would have undercut Gilead's sales of Truvada, its first combination-pill entry into a crowded class of nucleotide analogue reverse transcriptase inhibitors (NRTIs). And, Gilead was counting on Truvada—along with related parent drug Viread—to to grow its market share and continue to set it apart from the pack of pharmaceutical companies with similar offerings.

14. Sales of Truvada and its parent drug Viread would eventually lead Gilead to a $40 billion market capitalization and a quadrupling of its profits since 2004, to over $5 billion in 2009 and over $10 billion in 2015. The safer and more effective design Gilead had discovered, tested, and then rushed to provisionally patent, was shelved until Gilead had exhausted the profits it could earn from Truvada.

15. Gilead's decision to withhold a more effective and safer design, along with their

failure to warn, exacted a high price for Mr. Pierot, and caused severe bone mineral density and bone necrosis in both hips. In 2012, at the age of only 30, Mr. Pierot's hip bones had been so degraded by Gilead's medication that he was forces to have both hips replaced.

16. Had Gilead released Truvada in the safer and more effective design, Mr. Pierot, and countless other HIV-infected individuals could have been spared years, if not decades, of unnecessary bone and kidney toxicity.

17. Had Gilead adequately warned Mr. Pierot or his providers about the risk of bone mineral density loss, bone necrosis, and/or bone fracture, Mr. Pierot's medical providers could have prescribed one of the seven other antiviral medications available at that time.

18. Mr. Pierot's bone mineral density loss, bone necrosis, and resulting bilateral hip replacement at only 30 years old are a direct and proximate result of Gilead's wrongful conduct in designing, developing, manufacturing, testing, distributing, labeling, advertising, marketing, promoting, and selling an unsafe prescription antiviral drug, Truvada.

19. Mr. Pierot brings this action to recover medical and other expenses and all general and special damages related to his development of bone mineral density loss, bone necrosis, and hip replacement, and for general and specific future damages, and such other relief as requested herein for injuries suffered as a direct result of Mr. Pierot's ingestion of Truvada. At all times pertinent, Plaintiff used Truvada in a manner and dosage recommended by Gilead and prescribed by his doctor.

PARTIES

20. Plaintiff Christopher Pierot is a life-long Louisianan. Born and raised in Monroe, he remains a current resident. Mr. Pierot was prescribed and ingested Defendant's antiviral medication Truvada from 2008 through 2009. As a result of taking Truvada, Mr. Pierot suffered

extensive bone mineral density loss and bone necrosis, and in 2012 was forced to undergo the replacement of both hips. The double hip replacement greatly impacted Mr. Pierot's life. He suffered a great deal of pain during and after each surgery. He was forced to take time off from work and school, and was eventually forced to shift course of his chosen profession. Mr. Pierot's continues to suffer from pain and a reduction of his enjoyment of life from his double hip replacements.

21. Defendant Gilead Sciences, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 333 Lakeside Drive, Foster City, California 94404. Gilead is a pharmaceutical company that develops and commercializes prescription medicines, including Truvada, which were prescribed for and ingested by Plaintiff. Gilead was founded in 1987 by Michael L. Riordan, at the time a 29-year-old medical doctor interested in developing antiviral medications after he contracted dengue fever while working in the Philippines. Gilead's head of research and development, John C. Martin, a chemist and entrepreneur, became the CEO in 1996, a position he maintained until late 2016.

22. Defendant Gilead regularly conducts business within the State of Louisiana and derives substantial revenues from drugs consumed in the State of Louisiana. At all times relevant to this complaint, Gilead was engaged in the business of manufacturing, promoting, marketing, distributing, and selling pharmaceutical drugs, including Truvada, which is distributed throughout the State of Louisiana and within the Western District of Louisiana.

JURISDICTION AND VENUE

23. Jurisdiction is conferred upon this Court by 28 U.S.C. § 1332 because full diversity of citizenship exists between the parties. Defendant is incorporated and has its principal

place of business in states other than Louisiana, the state in which Plaintiff resides. Further, the amount in controversy as to the Plaintiff exceeds $75,000, exclusive of interest and costs.

24. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

25. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims occurred within the Western District of Louisiana.

FACTUAL ALLEGATIONS

26. Plaintiff Christopher Pierot (Plaintiff or Mr. Pierot) was prescribed and ingested Defendant Gilead's antiviral medication, Truvada from 2008 through 2009. Plaintiff took Truvada as part of "highly active antiretroviral therapy" ("HAART") to treat and manage HIV infection.

27. Truvada is the brand name of "tenofovir disoproxil fumarate" ("TDF"), which is a prodrug of the compound tenofovir. A prodrug is an inactive form of medication that, once ingested and metabolized, is converted by the body into the pharmacologically active form of the drug being delivered.

28. TDF is not the only prodrug form of tenofovir. TAF, tenofovir alfenamide, is another prodrug form.

29. Both TDF and TAF are taken orally and after absorption, the biologically-available tenofovir is passed into the blood.

30. Because TDF suffers from low oral bioavailability, it must be given in much higher doses to obtain the required therapeutic effects and prevent viral replication. TAF has superior bioavailability and achieves the needed therapeutic effects in doses that are a fraction of

those required for TDF.

31. Tenofovir, the active drug in both TDF and TAF, was initially synthesized more than thirty years ago by Antonín Holý at the Institute of Organic Chemistry and Biochemistry, Academy of Sciences of the Czech Republic in Prague. Dr. Holý was a long-time collaborator Dr. Erik De Clerq, a medical doctor and researcher at the Rega Institute for Medical Research in Leuven, Belgium.

32. In the mid 1980s, Dr. De Clerq, listed as one of the inventors of both TAF and TDF, often travelled to visit and conduct research at Bristol-Myers Squibb in Wallingford, CT. His host and then-BMS employee, John C. Martin, PhD, would later become the head of Research and Development, and recently-retired president of Gilead Sciences.

33. Dr. De Clerq has called his association with Drs. Holý and Martin the "Holý Trinity." "Tenofovir has been the lifetime achievement of the Holý Trinity, *i.e.*, Antonín Holý, myself, and John C. Martin." De Clerq, Erik, *An Odyssey in antiviral drug development—50 years at the Riga Institute: 1964-2014*, Acta Pharmaceutica Sinica B, Chinese Pharmaceutical Association, 2015;5(6):520-543.

34. Dr. De Clerq describes TDF as "the most successful drug ever developed for the treatment of AIDS, and it owed its success to the ingenuity of the chemist, A. Holý, but also the the foresight of the industrialist, by chance also a chemist, John C. Martin, who brought it to the market, and the medical doctor (myself) who served as the go-in between." *Id.*

35. In 1990 Mr. Martin left Bristol-Myers to become the head of Gilead's research and development. Focusing on how to combine HIV medications into fewer pills taken less frequently throughout the day, Mr. Martin, Gilead, and Dr. de Clerq discovered tenofovir among thousands of compounds they had licensed from Czech researchers.

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

37. While a powerful antiviral medication, tenofovir was never considered a medical breakthrough and had to be administered intravenously. To be able to market and sell tenofovir, as a one-pill per day, convenient treatment regimen, Gilead would need to develop prodrug formulations that could deliver the drug to the body in one pill and in a useable form.

38. After testing various prodrug forms, sometime in 1997, Gilead had isolated and put both TDF and TAF through pre-clinical studies regarding their potency, efficacy, and cytotoxicity.

39. Gilead's testing and research showed that TAF had "a 10-fold increase in antiviral activity relative to TDF and a 200-fold increase in plasma stability." "After 1 hour, [TAF] results in 10x and 30x the total intracellular concentration of [tenofovir]" as compared to TDF. "[TAF is] 2-3 orders of magnitude more potent than all other nucleosides or nucleotides."

40. A 1998 Gilead study conducted on beagles to analyze the oral administration of TAF confirmed these results. The TAF given to the beagles "result[ed] in a ~21-fold increase in [tenofovir exposure] as compared to [TDF]."

41. By July 21, 2000, more than a year before Viread (the first TDF-containing drug Gilead brought to market, and a predecessor and parent drug of Truvada) obtained FDA approval, Gilead submitted provisional patent applications to the U.S. and European Patent offices describing TAF, then called GS-7340, its enhanced uptake by target cells, reduced cytotoxicity, and superior stability and concentration compared to TDF. *See* United States Provisional Patent Application No. 60/220021; European Provisional Patent Application Number 01961695.2. The provisional patent applications cited Gilead research dating back to 1997 showing TAF was 2-3 times more potent than Truvada and that it could obtain concentrations of

tenofovir in target cells that were ten to thirty times higher than those attainable with Truvada. "As shown, [TAF is] 2-3 orders of magnitude more potent than all other nucleotides or nucleosides."

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

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

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

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

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

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

44. In May 2001, after demonstrating TAF's greater potency, concentration, efficacy, and bioavailability, Gilead submitted its TDF design to the FDA for accelerated approval under 21 CFR 314.108(b)(2).

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

46. Gilead submitted TDF for approval as Viread on the basis of two incomplete clinical trials conducted on treatment-experienced populations. While animal toxicology studies of TDF had shown that bones and kidneys were target organs of toxicity and that the toxicity caused decreased bone mineral density and osteomalacia, Gilead's clinical trials collected only limited data related to bone metabolism or kidney toxicity.

47. In the course of pre-approval meetings for Viread, Gilead fought to have the FDA agree with its belief that "there is no evidence that tenofovir has a direct effect on bone." But, the FDA had documented sixteen bone fractures in clinical testing, and noted Gilead had documented fifteen. The individual bone fracture data was omitted from Viread's package insert.

48. Viread was approved for sale on October 26, 2001.

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

50. As Viread continued to corner the market, Gilead ignored the risks TDF continued to present and put its TAF design and research on the shelf to focus on promoting, selling, and making a profit from Truvada.

51. In April 2002, as prescriptions for TDF were growing along with Gilead's market share, Gilead's research continued to confirm TAF's diminished toxicity and TDF's verified risks to bone and kidneys. But, Gilead did not publish this research, did not conduct clinical trials

of TAF, did not change its prescribing information, and did not instruct its sales representatives to begin informing doctors that the toxicities associated with TDF could be eliminated with a new, better drug.

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

53. In late 2003, with full knowledge that TAF was a safer and more effective design alternative, Gilead prepared another application to the FDA for a TDF drug, Truvada—the first TDF-combination drug it would use to extend the profitability of its TDF patent.[2] At this time, Gilead's own clinical studies continued to show that TDF presented toxicity risks to kidneys and bones.

54. Truvada, the medication Mr. Pierot was prescribed, is a fixed-dose combination pill consisting of TDF and emtricitabine, another NRTI developed by Gilead that had been approved for sale on July 2, 2003.

55. Truvada was approved for sale on August 2, 2004.

56. In spite of the clear and growing need to investigate and mitigate the risks associated with TDF, in October 2004, Gilead's CEO John C. Martin suddenly announced, "the company is discontinuing its development program" for TAF.

57. Although Gilead withdrew TAF from clinical development, it continued its

[2] Truvada consists of three different fixed-dose combinations of tenofovir delivered as TDF combined with emtricitabine, a nucleoside antiviral.

financial development of the compound and between October 2004 and May 2005, Gilead secured its interest in the superior prodrug and applied for seven patents associated with TAF.

58. As TAF sat on the shelf, Gilead continued to combine TDF with other drugs in order to further extend its monopoly profits and market share.

59. On July 12, 2006, the TDF-combination pill Atripla was approved for sale. Atripla had over $2.2B in U.S. sales in 2015.

60. On August 10, 2011, the TDF-combination pill Complera was approved for sale. Complera had almost $800M in U.S. sales in 2015.

61. On July 16, 2012, the TDF-combination pill Truvada was given an additional indication and approved for sale to non-HIV infected patients as part of a pre-exposure prophylaxis program designed to prevent the contraction and spread of the virus. Truvada, for both indications, earned over $2B in 2015.

62. And on August 27, 2012, the TDF-combination pill Stribild was approved for sale. Stribild earned $1.5B in sales in 2015.

63. Although it synthesized TAF in the late 1990s, put through pre-clinical testing in the 90s 2000, and 2001, and then patented in 2004 and 2005, Gilead did not apply for approval from the FDA to sell a TAF-containing drug until November 5, 2014.

64. Indeed, the first TAF-containing drug, Genvoya, was not released for sale until November 5, 2015. Gilead's patent on Truvada was set to expire just more than a year later, in 2017.

65. Gilead's tactics have allowed it to reap outsized profits. In 2015, Gilead was able to earn 90% Non-GAAP Product Gross Margins. Gilead's tactics have led the New York Times to comment, "Gilead now is faced with figuring out *what to do with all the cash it is*

generating."[3]

66. Gilead's high profits come from the steep costs of its drugs. High prices of drugs such as Gilead's Viread ($10,848) and Truvada ($18,456 per year) limit patient access either through exorbitant out of pocket-costs or co-pays, limitations in existing insurance, and rationing of these high-priced pills.

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

68. Not only did Gilead hide a safer alternative design in an attempt to push other designs out of the market, it also failed to adequately warn Mr. Pierot and his doctors about the side effects associated with Truvada's toxicity.

69. All TDF-containing medications have package inserts and labeling based on Viread's original package insert. Truvada's package insert does not adequately warn of the risks of bone and kidney toxicity, chronic kidney disease, bone mineral density loss, bone necrosis, or fractures to patients without prior bone or kidney issues.

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

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

72. In addition to failing to adequately warn Mr. Pierot or his doctors of the risks to bones and kidneys associated with TDF, Gilead has engaged in an extensive overmarketing

[3] Andrew Pollack, *Sales of Solvadi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion,* NEW YORK TIMES (February 4, 2015) (emphasis added).

campaign. As early as 2001, right after Viread's FDA approval, Gilead affirmatively and publicly misrepresented TDF's safety profile through its sales representatives and CEO, claiming that TDF was a "miracle drug," had "no toxicities," was "benign," and "extremely safe."

73. Gilead's CEO at the time, Dr. John C. Martin, would often refer to TDF as a miracle drug at sales meetings. He did so because of his stated belief that Gilead needed to overcome the perception in the medical community that Viread was like Gilead's previous HIV drugs and would likely cause kidney damage.

74. Even after Gilead was reprimanded by the FDA in 2002 and 2003 for falsely claiming TDF had no toxicities and bore no risk to a patient's kidneys or bones, Gilead continued to misrepresent the risks through its Viread prescription inserts and patient information sheets, which similarly downplayed the risks and misrepresented that toxicity, bone, or kidney damage was primarily a risk for patients with pre-existing kidney or bone issues.

75. Gilead made these misrepresentations even though it knew TDF had a high potential for toxicity and loss of bone mineral density in all patients. In its early stages of development, TDF animal toxicology studies showed that the bones and kidneys were the target organs for toxicity and that the bone toxicities included osteomalacia and decreases in bone mineral density.

76. Clinical studies and adverse event reports from as early as 2001 and 2002 document severe renal deficiencies and toxicity in patients without any history of kidney problems. A 2003 case report found fatal renal insufficiency in a patient with only mild previous renal impairment. And studies as early as 2002 associate TDF with acute decreases in bone mineral density and bone loss.

77. Again, while Gilead's CEO was claiming TDF was a risk-free, miracle drug,

reports and studies advised monitoring patients closely for early signs of toxicity, kidney failure, or bone mineral density loss, even several months after initiation of treatment and further recommended discontinuing treatment as soon as possible to avoid the risk of permanent changes or damage.

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

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

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

FRAUDULENT CONCEALMENT AND TOLLING

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

82. The running of any prescriptive period has been tolled by reason of Defendant's fraudulent concealment. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff, Christopher Pierot, and his physician(s) the true risks associated with the use of Truvada.

83. As a result of Defendant's actions, Plaintiff and his physician(s) were unaware,

and could not reasonably have known or have learned through reasonable diligence, that he had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendant's acts and omissions.

COUNT ONE
LOUISIANA PRODCUTS LIABILITY ACT
DESIGN DEFECT LSA R.S. 9:2800.56

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

85. At all times material to this action, Defendant was responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling its prescription drug Truvada.

86. Truvada was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendant.

87. Truvada is defective and unreasonably dangerous because both before FDA approval and at the time it left Gilead's control, Gilead knew that a Truvada designed with TAF was capable of preventing Plaintiff's bone mineral density loss, bone necrosis, and hip replacement.

88. In the alternative, Truvada is defective and unreasonably dangerous because both before FDA approval and at the time it left Gilead's control, there were other, safer antiviral medications that Plaintiff's doctors could have prescribed.

89. Truvada is further defective and unreasonably dangerous because the risk, danger, and gravity of bone mineral density loss, bone necrosis, and/or bone fracture, far outweighed any adverse effects on the utility of Truvada and far outweighed any possible burden on Gilead in

adopting the alternative design.

90. In addition, at the time the Truvada used by Plaintiff left Defendant's control, there were other practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Mr. Pierot's injuries without impairing the reasonably anticipated or intend function of the product. These safer alternatives designs were economically and technologically feasible, and also would have prevented or significantly reduced the risk of Mr. Pierot's injuries without substantially impairing the product's utility.

91. As a direct and proximate result of Truvada's defective design, Plaintiff has suffered and will continue to suffer severe and permanent injury and/or damage.

COUNT TWO
LOUISIANA PRODCUTS LIABILITY ACT
INADEQUATE WARNING LSA R.S. 9:2800.57

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

93. Defendant researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced Truvada into the stream of commerce, and in the course of the same, directly advertised or marketed Truvada to consumers or persons responsible for consumers, and therefore, had a duty to both Mr. Christopher Pierot directly and his physician(s) to warn of risks associated with the use of the product.

94. Defendant had a duty to warn of adverse drug reactions, which they knew or had reason to know can be caused by the use of Truvada and/or are associated with the use of Truvada.

95. The Truvada manufactured and/or supplied by Defendant was defective due to

inadequate post-marketing warnings and/or instructions because, after Defendant knew or should have known of the risks of bone mineral density loss, bone necrosis, and/or hip replacement from Truvada use, they failed to provide adequate warnings to consumers of the product, including Plaintiff and Plaintiff's physician(s), and continued to aggressively promote Truvada as safe for kidneys and bones.

96. Due to the inadequate warnings regarding the risk of bone mineral density loss, bone necrosis, and/or bone fracture in patients without a history of bone problems, Truvada was in a defective condition and unreasonably dangerous at the time that it left Defendant's control.

97. Defendant failed to adequately warn Plaintiff and Plaintiff's prescribing physician(s) of human and animal results in preclinical studies linking Truvada to bone toxicity and bone mineral density loss in patients with no prior bone issues.

98. Had Plaintiff been adequately warned of the side effects of the Defendant's Truvada, Plaintiff would not have purchased or taken Truvada and could have chosen to request other treatments or prescription medications.

99. Upon information and belief, had Plaintiff's prescribing physician(s) been adequately warned of the potential side effects of the Defendant's Truvada, Plaintiff's prescribing physician(s) would have discussed the risk of bone mineral density loss with Plaintiff and/or would not have prescribed it.

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

COUNT THREE
LOUISIANA PRODCUTS LIABILITY ACT
BREACH OF EXPRESS WARRANTY LA. R.S. 9:2800.58

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

102. Defendant expressly warranted that Truvada was safe for its intended use and as otherwise described in this Complaint. Truvada did not conform to these express representations, including, but not limited to, the representation that it was well accepted in patient and animal studies, the representation that it was safe, and the representation that it did not have high and/or unacceptable levels of permanent bone mineral density loss, bone necrosis, and/or bone fracture, and that it would improve health, maintain health, and potentially prolong life.

103. These express warranties represented by the Defendant were a part of the basis for Plaintiff's use of Truvada and Plaintiff and/or his physician relied on these warranties in deciding to use Truvada.

104. At the time it made the express warranties, the Defendant had knowledge of the purpose for which the Truvada was to be used and warrantied it to be in all respects safe, effective, and proper for such purpose.

105. Truvada does not conform to these express representations because Truvada is not safe or effective and may produce serious side effects, including, among other things, bone mineral density loss, bone necrosis, and/or bone fracture.

106. As a result of the foregoing breach of express warranties Christopher Pierot was caused to suffer bone mineral density loss, bone necrosis, and a double hip replacement, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and any and all life complications caused by Plaintiff's bone mineral density loss, bone necrosis, and a double hip replacement.

COUNT FOUR
BREACH OF WARRANTY IN REDHIBITION

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

108. Truvada contains a vice or defect which renders it useless or its use so inconvenient that consumers would not have purchased it had they known about the vice or defect.

109. Pursuant to Louisiana Civil Code article 2520, a seller warrants the buyer against redhibitory defects, or vices, in the thing sold.

110. In accordance with Louisiana Civil Code article 2545, a manufacturer of a product, such as Gilead is of Truvada, is deemed to be aware of its redhibitory defects.

111. Truvada possesses a redhibitory defect because it was not manufactured and/or marketed in accordance with industry standards and/or is unreasonably dangerous, as described above. This defect renders Truvada so useless or inconvenient that it must be presumed that had Plaintiff or his physician known of the defect, he would not have been prescribed or ingested Truvada.

112. Defendant was aware of the substantial risks from using Truvada but failed to fully disclose those risks to the Plaintiff or his physicians.

113. Had Plaintiff or his physicians been made aware of the defects contained in Truvada, he would not have purchased Truvada. This characteristic rendered Truvada unfit for its intended purposes.

114. Defendant is liable to Plaintiff under the theory of redhibition as a consequence of the sale to Plaintiff of a product unfit for its intended use.

115. Plaintiff is entitled to the return of purchase price paid, including, but not limited to, insurance co-payments, interest on these amounts from the date of purchase, attorneys' fees

and costs, pecuniary and non-pecuniary damages, as well as any other legal and equitable relief to which Plaintiff may be entitled.

DAMAGES

116. As a result of Gilead's acts, omissions, and failures described herein, Plaintiff Christopher Pierot has sustained substantial injuries, permanent disability, and damages, including, but not limited to, severe and permanent bodily injury.

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

PUNITIVE DAMAGES

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

PRAYER FOR RELIEF

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

a. Past medical and incidental expenses, according to proof;

b. Past and future loss of earnings and/or earning capacity, according to proof;

c. Past and future general damages, according to proof;

d. Punitive and exemplary damages in an amount to be determined at trial;

e. Pre-judgment and post-judgment interest;

f. The costs of this action, including reasonable attorneys' fees; and

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

JURY DEMAND

Plaintiff hereby requests a trial on the merits by jury, pursuant to Fed. R. Civ. P. 38.

DATED: July 27, 2018

Respectfully submitted,

/s/ Michelle Rutherford
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