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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

MICHAEL LUJANO, individually, JONATHAN C. GARY, individually. **Plaintiff,** **v.** **GILEAD SCIENCES, INC.** **Defendant.**	**Case No. _____** **COMPLAINT FOR DAMAGES** ***Unlimited Civil Action*** 1. **STRICT PRODUCTS LIABILITY – DESIGN DEFECT AND FAILURE TO WARN** 2. **NEGLIGENT PRODUCTS LIABLITY – DESIGN DEFECT AND FAILURE TO WARN;** 3. **BREACH OF IMPLIED WARRANTY;** 4. **BREACH OF EXPRESS WARRANTY** **DEMAND FOR JURY TRIAL**

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

I. INTRODUCTION

Plaintiffs were prescribed and ingested Defendant Gilead's antiviral medications, Truvada and Atripla for many years. Plaintiffs took Gilead's drugs as part of "highly active antiretroviral therapy" ("HAART") to treat and manage HIV infection.

Viread is the brand name of "tenofovir disoproxil fumarate" ("TDF"), which is a prodrug of the compound tenofovir.[1] TDF works by blocking the protein that HIV needs to replicate itself in the human body. TDF is Viread's only active ingredient. Truvada and Atripla are both fixed dose combination tablets containing 300 milligrams of TDF and one or two additional drugs. Truvada combines TDF with 200 milligrams of emtricitabine, and Atripla adds one more medication to that combination, 600 mg of efavirenz.

At the time Gilead designed, manufactured, and sold Truvada in 2004, and Atripla in 2006, Gilead knew, or should have known, that TDF was highly toxic in the doses prescribed and risked permanent and possibly fatal damage to the kidneys and bones. Instead of fully and completely investigating and disclosing the known and knowable risks associated with TDF, Gilead ignored and affirmatively misrepresented them.

Before Gilead designed, manufactured, and sold Truvada and Atripla, and years before the U.S. Food and Drug Administration ("FDA") approved these medications, Gilead had discovered and begun researching a safer and more effective design for the delivery of tenofovir to the body, tenofovir alafenamide ("TAF"). Indeed, even before Viread was approved by the FDA in 2001, Gilead knew that a tenofovir prodrug design using TAF instead of TDF would reduce the risks of toxicity and damage to kidney and bones.

But, because Gilead enjoyed monopoly profits on its TDF-containing drugs, including Truvada and Atripla, resulting from its patent on TDF, Gilead chose to withhold TAF as the

[1] Prodrugs are medicines that are not converted into their active form until they are processed inside the body. TDF is taken orally and after absorption it passes into the blood.

prodrug design for Truvada and Atripla. Designing Truvada and Atripla with TAF—which Gilead later did in 2014 and 2016 under the names Odefsy and Descovy—would have eliminated the need for TDF-containing Truvada and Atripla. This decision would have helped to avoid needles (and countless) injuries and damages, but it would have reduced Gilead's monopoly profits from the sale of TDF.

A TAF design would have greatly improved and possibly even saved the lives of patients taking Truvada and Atripla, many of whom, like Plaintiffs, were on Gilead's medications for years. If Gilead had designed Truvada and Atripla with TAF, far fewer people, like the Plaintiffs, would have developed bone loss or kidney damage as a result of taking Gilead's medications. Gilead has long known of TAF's superior safety profile but has consistently chosen to place market share and profitability over patient safety.

As early as April 2002, as prescriptions for TDF were growing along with Gilead's market share, Gilead was paying doctors to conduct studies of the safer prodrug TAF in patients around the country. These studies showed that TAF was far less toxic and confirmed that TDF's low absorption, high dosage, and potential bone and renal toxicity were real risks. 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.

Gilead took none of these steps because TDF sales were booming and Viread had begun to corner the market in antiviral treatments for HIV. As Gilead kept doctors and patients in the dark about the toxicity, kidney, and bone loss risks associated with TDF, it could continue to increase its market share with TDF. 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.

Gilead's delay in conducting TAF clinical trials deprived those suffering from HIV of TAF for more than a decade. These patients were forced to take TDF, which because of TDF's lower absorption rates caused and exacerbated higher bone and kidney toxicities. It is possible

that HIV patients suffered from ten years of additional accumulated kidney and bone toxicity using TDF while Gilead kept TAF on the shelf.

If Gilead had chosen to develop tenofovir in the safer and more effective TAF version, TDF would lose marketability—it was less effective and had far higher risks—and Gilead's profits from TDF would decrease. By holding on to its research and shelving TAF, Gilead could patent TAF separately and save it for development when their patent and exclusivity on TDF ran out, in twenty years.

In late 2003, Gilead continued to study TAF at the same time it was preparing its application to the FDA for Truvada—the first TDF-combination drug it would use to extend the profitability of its TDF patent.[2] Also at this time, Gilead's own clinical evidence of TDF's toxicity and risks to kidneys and bones was building along with evidence from other studies. And yet, 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 announced, "the company is discontinuing its development program" for TAF.

Gilead's claim that it would discontinue research into TAF was a misrepresentation intended to mislead the purchasing public, including prescribing doctors and patients taking TDF, into continuing to prescribe and take TDF.

Indeed, Gilead did not discontinue development of TAF. Instead, between October 2004 and May 2005, Gilead applied for seven patents associated with it. By hiding research about TAF's superior safety profile and efficacy, and by continuing to downplay the risks associated with TDF, Gilead continued its scheme to mislead the public and maximize profits for TDF.

Gilead knew of TAF's superior profile and the risks associated with TDF at least as far back as 2000. By the time Truvada and Atripla were submitted for approval to the FDA in 2004 and 2006, Gilead had long known 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 associated with TDF. Gilead failed to do this. Instead, Gilead

[2] Truvada consists of three different fixed-dose combinations of tenofovir delivered as TDF and emtricitabine.

misrepresented the safety and benefits of TDF and failed to provide prescribing physicians and their patients with the information they needed to safely and reasonably prescribe and take Gilead's drugs.

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]

Gilead's high profits come from the steep costs of its drugs. High prices of drugs such as Gilead's 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.

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. Gilead spent approximately that much in 2015 on research and development but its profits in 2015 were $18.1 billion.

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

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, Truvada, and Atripla prescription inserts and patient information sheets, which similarly downplayed the stated risks and misrepresented that toxicity, bone, or kidney damage was primarily a risk for patients with pre-existing kidney or bone issues.

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

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

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.

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 reported 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.

Again, as early as 2002 and 2003, while Gilead's CEO was claiming TDF was a risk-free, miracle drug, these reports and studies advised monitoring patients closely for early signs of toxicity, kidney failure, or bone 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.

Long before Truvada and Atripla were submitted for approval to the FDA in 2004 and 2006, 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 warn of any known or scientifically knowable risks associated with use of TDF. Instead, Gilead misrepresented the safety and benefits of TDF and failed to provide prescribing physicians and their patients with the information they needed to safely and reasonably prescribe and take Gilead's drugs.

Gilead had a duty to design and manufacture Truvada and Atripla in a manner that met the safety expectations of ordinary consumers and/or their prescribing physicians. Instead, Gilead designed Truvada and Atripla to contain TDF, a prodrug it knew caused bone and kidney damage, so that they could maximize their profits and monopoly on TDF.

Plaintiffs seek general and punitive damages and seek to hold Gilead accountable for its malicious and profit-driven refusal to design Truvada and Atripla in a safe and effective manner.

II. THE PARTIES

Plaintiff Michael Lujano is a resident of the State of California and the County of Los Angeles. Mr. Lujano was prescribed and ingested Gilead's prescription medication Truvada from

2004 until 2009. Mr. Lujano was prescribed and ingested Gilead's prescription medication Atripla from 2009 until 2015. In 2016, at the age of 35, Mr. Lujano was diagnosed with osteopenia and osteoporosis of the spine, neck, and hip. Mr. Lujano was unaware that his injuries were caused by Truvada and Atripla until within two years of the filing of this complaint.

Plaintiff Jonathan C. Gary is a resident of the State of California and the County of San Diego. Mr. Gary was prescribed and ingested Gilead's prescription medication Truvada from 2001 until 2011. In 2010 Mr. Gary was diagnosed with Fanconi syndrome. In 2017, at the age of 59, Mr. Gary was diagnosed with osteopenia and osteoporosis. Mr. Gary was unaware that his injuries were caused by Truvada until within two years of the filing of this complaint.

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 and Atripla, which were prescribed for and ingested by Plaintiffs.

III. JURISDICTION AND VENUE

This Court has jurisdiction over the subject matter of this action pursuant to California Code of Civil procedure § 410.10 because a substantial portion of Gilead's acts and Plaintiffs' injuries occurred within Los Angeles County, California. This court has personal jurisdiction over Defendant Gilead Sciences, Inc. as it is a California corporation.

Venue is proper in the County of Los Angeles pursuant to California Code of Civil procedure §§ 395 and 395.5 because Gilead does business in Los Angeles County and a substantial portion of Gilead's negligence, misrepresentations, incomplete and misleading warnings, and fraudulent marketing practices occurred in the County of Los Angeles.

IV. GENERAL ALLEGATIONS

a. Gilead Prepares TDF for Market

Tenofovir was discovered in 1984 by scientists in the Czech Republic. Gilead bought the rights to sell Tenofovir in 1997. The original formulation of Tenofovir held little sales potential, however, because it had to be given intravenously. Gilead scientists modified the chemical

composition to create a drug that could be taken orally. The modified chemical composition is tenofovir disoproxil ("TDF"). The Food and Drug Administration approved TDF under the brand name Viread in October 2001.

TDF became the backbone of many HIV treatment regimes. The use of multiple drugs to treat HIV is known as Highly Active Antiretroviral Therapy ("HAART"). HAART is aimed at reducing a patient's viral load and thus maintaining a patient's immune system. HAART regimens generally consist of three drugs: two drugs from the class of drugs known as Nucleoside Reverse Transcriptase Inhibitors ("NRTIs") and one drug from classes of drugs known as Non-Nucleoside Reverse Transcriptase Inhibitors ("NNRTI"), Protease Inhibitors ("PI"), or Integrase Nuclear Strand Transfer Inhibitors ("INSTI").

Tenofovir is an NRTI and is frequently used in HAART therapies. In addition to making TDF available as a standalone drug product under the brand name Viread, Gilead incorporated TDF in fixed dose combination pills including Atripla, Truvada, Stribild, and Complera.

b. Gilead Knew of Bone and Kidney Risks Before FDA Approved TDF

Originally marketed as a stand-alone medication, Gilead obtained FDA approval to manufacture and sell TDF in October 2001 under the brand name Viread. Yet, before Gilead had finalized Viread for FDA approval in 2001, and long before either Truvada or Atripla were approved in 2004 and 2006, Gilead knew that TDF's low absorption rate meant it had to be administered in high doses to be effective. Before taking Viread to market, Gilead also knew that TDF in high doses placed immense pressure on the kidneys, the body's predominate method of eliminating the drug.

Since scientists first synthesized TDF in 1997, studies of TDF showed that it could cause significant kidney damage and bone toxicity. This damage includes decreases in bone mineral density, osteopenia, osteoporosis, osteoporosis with pathologic fracture, Fanconi syndrome, chronic kidney disease, and end stage kidney disease.

The toxicity of TDF known to Gilead at the time it was developing Viread in 2001 is particularly alarming because Gilead also knew and indeed likely intended that HIV-infected patients would receive TDF treatment for decades, allowing the toxicity to build overtime, but

ensuring the patient would remain a purchaser of Gilead's TDF, at least until Gilead began marketing TAF, and essentially ensuring the patient would be a long-term Gilead customer.

When TDF was approved in October 2001, the FDA required Gilead to study whether it would harm humans.[4] The FDA noted that Gilead "did not evaluate tenofovir DF in individuals with renal insufficiency" and "did not determine specific active secretion pathways" for the drug. *Id.* Along with the FDA's recommendations for human study, it made clear that Gilead must properly examine and disclose the side effects TDF would have on the kidneys and whether it would build up to toxic levels in the body. *Id.*

c. Gilead Studies Safer Prodrug TAF, Hides Results

Gilead, however, has been more interested in maximizing the profits it has derived from TDF than it has been in disclosing the risks associated with the drug. About six or seven months before Viread was approved, in April 2001, Gilead scientists published research on a different prodrug of Tenofovir, called Tenofovir Alafenamide ("TAF"). In an attempt to reduce known side effects of TDF, Gilead conducted test tube and animal research studies on the prodrug and in April 2002, Gilead paid doctors to conduct clinical studies of TAF in HIV patients around the country.[5]

After learning that TAF had a higher absorption rate and largely avoided the bone and kidney toxicity associated with TDF, Gilead did not substitute TAF for TDF in the design of any of its drugs, including Viread, Truvada, and Atripla. In an act of extreme malice, Gilead also refused to publish its research on TAF, choosing instead to keep HIV-infected patients and their doctors in the dark about the full risks associated with TDF, along with the solution to those risks, for over a decade.

In 2014, as Gilead's patent on TDF approached its expiration and Gilead faced a sharp decrease in profits that would result from competition entering the market for TDF-containing

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[4] *Food and Drug Administration,* CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW, New Drug Application (Viread) No. 21-356 pp. 1-7 (May 1, 2001).

[5] Martin Markowitz et al., *Phase I/II study of the pharmacokinetics, safety and antiretroviral activity of tenofovir alafenamide, a new prodrug of the HIV reverse transcriptase inhibitor tenofovir, in HIV-infected adults,* J. ANTIMICROBIAL CHEMOTHERAPY, 69:1362-1369 (2014).

drugs, Gilead decided to release the results of the TAF studies it began conducting in 2001. These studies were cited in support of three new combination drug applications containing TAF and approved, respectively, in November 2015 (Genvoya), March 2016 (Odefsy), and again in April 2016 (Descovy).

d. The FDA Reprimands Gilead for its Misleading TDF Marketing

Just after Viread's approval and in the two years leading up approval of Truvada, the FDA twice issued warning letters to Gilead over its TDF marketing practices, stating that their sales representatives had violated the law by giving doctors and patients false and misleading information regarding TDF's side effects. According to a 2002 FDA Warning Letter, Gilead salespeople falsely stated that TDF had "no toxicities," was "benign," and was "extremely safe." A 2003 FDA Warning Letter took the uncommon step of requiring Gilead to retrain its sales representatives to provide accurate information regarding the significant side effects associated with TDF and comply with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 352.

In a shareholder lawsuit filed in 2009, a former Gilead employee and complaining witness stated that Gilead CEO Dr. John C. Martin would refer to Viread as a miracle product all the time at meetings. Another former employee and complaining witnesses confirmed this information and stated that Dr. Martin promoted Viread as a miracle drug because 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.

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.

e. Gilead Misrepresents Risks Associated with Truvada

Gilead's prescribing information and patient information sheets for Truvada did little to correct the tide of misrepresentations unleashed by its sales force and CEO only months before Truvada's launch into the market in 2004. Truvada's prescribing information failed to correct

prior misrepresentations regarding the safety and efficacy of TDF and continued to misrepresent and minimize the risk of toxicity and bone and kidney damage. Where Gilead did list potential patient concerns, it misrepresented the risks as primarily for already-renally impaired or bone-compromised patients.

Truvada's original prescribing information insert and patient information sheet represent the risks of toxicity and bone and kidney damage as primarily a concern for patients with a history of bone and kidney problems. It was known to Gilead, or scientifically knowable, that the high doses of tenofovir necessary to make it bioavailable as TDF could lead to toxicity in the kidneys in all patients, even those without a history of renal dysfunction or other risk factors. As early as 2003, a case report had been published showing lethal renal toxicity in a patient without any history of renal impairment.

Truvada's original prescribing information also misrepresents the risks to bone toxicity and bone mineral density loss. Mentioning "bone effects" on the twentieth page of the prescribing information sheet, it summarizes a 48-week clinical TDF study on baseline bone mineral density. Although it notes that decreases in BMD were seen at the lumbar spine and hip for patients taking TDF, it claims that the "clinical significance of the changes in BMD" were "unknown" and that bone monitoring should only be considered for patients "with a history of pathologic bone fracture or at substantial risk for osteopenia." Referring to the same 48-week study, Gilead further misleadingly claimed that "there was no increased frequency of established toxicities" associated with taking TDF.

Gilead's Truvada patient information sheet, provided at the end of the fifty-six page prescribing information packet, compounds the misrepresentations by continuing to downplay the risks associated with Truvada, limiting its warnings to patients with "bone problems" or "kidney problems in the past or tak[ing] other medicines that can cause kidney problems." The patient information sheet further falsely claims it "is not known whether long-term use of TRUVADA will cause damage to your bones."

While Truvada's prescribing information and patient information sheets have undergone changes over the years, the current prescribing information and patient information sheets still

fail to sufficiently warn consumers and their physicians about the risk of toxicity and severe bone and kidney problems.

Truvada's current prescribing information and patient information sheet make sparse mention of the risks associated with long-term TDF use in patients without a history of bone problems and affirmatively misrepresent that such risks are primarily present for patients with a clinical history of bone and renal issues.

Gilead knew or should have known as early as 2001 that TDF posed risks to the kidneys and bones of all patients, not just those with a clinical history of kidney and bone problems. Gilead not only failed to warn of these risks but made affirmative misrepresentations that such risks were posed primarily to patients with a history of kidney and bone problems.

f. Gilead Misrepresents Risks Associated with Atripla

In 2006, when Gilead began marketing and selling Atripla, it provided a prescribing information and patient information sheet with misrepresentations nearly identical to those in the Truvada and Viread materials.[6]

Atripla's original prescribing information generally limited its warnings to patients with a history of bone and kidney problems and similarly inaccurately claimed that the effects of TDF on BMD, long-term bone health, and future fracture risk were "unknown."

Atripla's patient information sheet maintained the misrepresentations contained in Truvada's and Viread's materials, listing "kidney problems" as a possible side effect for patients with "kidney problems in the past or tak[ing] other medicines that can cause kidney problems" and "changes in bone mineral density" "[i]f you have had bone problems in the past," while also claiming it was "not known whether long-term use of ATRIPLA will cause damage to your bones."

Atripla's current prescribing information and patient information sheet continue to limit warnings for bone and kidney problems and toxicity as risks primarily affecting patients with a history of bone or kidney problems.

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[6] All of the prescribing information and patient information sheets for both Atripla and Truvada refer back to Gilead's materials for Viread, the single component name brand TDF that is contained in both Atripla and Truvada.

Atripla's prescribing information and patient information sheet make sparse mention of the risks associated with long-term TDF use in patients without a prior history of bone problems and affirmatively misrepresent that such risks are primarily present for patients with a clinical history of bone and renal issues. Gilead knew, or should have known, in 2006 that TDF posed risks to the kidneys and bones of all patients, not just those with a clinical history of kidney and bone problems. Gilead not only failed to warn of these risks but made affirmative misrepresentations that such risks were posed primarily to patients with a history of kidney and bone problems.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECT AND FAILURE TO WARN
(By Plaintiffs against Defendant)

Plaintiffs fully reallege and incorporate by reference each allegation made above as if fully set forth here and further allege as follows:

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 Truvada and Atripla.

Gilead designed Truvada and Atripla to contain TDF as the prodrug formulation of tenofovir at least three years before Gilead submitted either Truvada or Atripla to the FDA for approval, in 2004 and 2006 respectively.

Gilead chose to design Truvada and Atripla with the TDF prodrug formulation so that they could make maximize profits on sales of TDF. Gilead delayed releasing the TAF prodrug formulation of Truvada and Atripla until at least 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.

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

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

Gilead placed the Truvada and Atripla 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. Truvada and Atripla also 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.

The Truvada and Atripla Gilead manufactured and supplied was also defective due to inadequate warning or instruction because Gilead knew or should have known that Truvada and Atripla created a serious risk of harm to consumers and Gilead failed to adequately warn consumers of the risks, including Plaintiffs.

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

The Truvada and Atripla Gilead manufactured and supplied was defective due to inadequate warning and inadequate testing.

The Truvada and Atripla Gilead manufactured and supplied was defective due to inadequate post-market warnings and instructions, because Gilead knew or should have known of the risk of serious injury from Truvada and Atripla, however Gilead failed to provide adequate warnings to users and consumers of the product, including Plaintiffs, and continued to promote the product.

On or before 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.

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

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

Gilead was motivated by their own financial interest in the continuing uninterrupted manufacture, supply, sale, marketing, packaging and advertising of Truvada and Atripla.

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

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.

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.

As a proximate and legal result of the defective and unreasonably dangerous condition of Truvada and Atripla Gilead tested, manufactured and supplied, and the lack of adequate use instructions and warnings, Plaintiffs were caused to suffer the injury and damages.

SECOND CAUSE OF ACTION
NEGLIGENT PRODUCTS LIABLITY – DESIGN DEFECT AND FAILURE TO WARN
(By Plaintiffs against Defendant)

Plaintiffs fully reallege and incorporate by reference each allegation made above as if fully set forth here and further allege as follows:

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

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

Gilead was negligent in the design, manufacture, testing, advertising, warning, marketing and sale of Truvada and Atripla.

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

Gilead knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of Gilead's failure to exercise ordinary care as described above.

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

As a proximate and legal result of Gilead's negligence, said Plaintiffs were caused to suffer the herein described injuries and damages.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(By Plaintiffs against Defendant)

Plaintiffs fully reallege and incorporate by reference each allegation made above as if fully set forth here and further allege as follows:

At all times mentioned in this Complaint, Gilead manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold Truvada and

Atripla, and prior to the time it was prescribed to Plaintiffs, Gilead impliedly warranted to Plaintiffs, and their physicians and healthcare providers, that Truvada and Atripla were of merchantable quality and safe for the use for which they were intended.

Plaintiffs and their physicians and healthcare providers relied on Gilead's skill and judgment in using Truvada and Atripla.

The product was unsafe for its intended use was not of merchantable quality, as warranted by Gilead, in that it had very dangerous propensities when put to its intended use and would cause severe injury to the user. Truvada and Atripla were unaccompanied by sufficient warnings of their dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.

As a proximate and legal result of the defective and unreasonably dangerous condition of the Truvada and Atripla manufactured and supplied by Gilead, Plaintiffs were caused to suffer and will continue to suffer the injuries and damages described herein.

After Plaintiffs were made aware that their injuries were a result of Truvada and Atripla, notice was duly given to Gilead of the breach of said warranty.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(By Plaintiffs against Defendant)

Plaintiffs fully reallege and incorporate by reference each allegation made above as if fully set forth here and further allege as follows:

The aforementioned manufacturing, compounding, packaging, designing, distributing, testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising, promoting, supplying and selling of Truvada and Atripla was expressly warranted to be safe for Plaintiffs' use and other members of the general public.

At the time of the making of the express warranties, Gilead knew the purpose for which Truvada and Atripla were to be used and warranted the same to be in all respects, fit, safe, and effective and proper for such purpose. Truvada and Atripla were unaccompanied by warnings of their dangerous propensities that were known or knowable at the time of distribution.

In using Truvada and Atripla, Plaintiffs and their physicians reasonably relied on

Gilead's skill and judgment and on the express warranty. The warranty and representations were untrue in that Truvada and Atripla were unsafe and, therefore, unsuited for the uses for which they were intended.

Truvada and Atripla could and did cause Plaintiffs to suffer and continue to suffer the above-described injuries and damages.

PRAYER FOR RELIEF

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

1. For general damages to be proven at trial;
2. For past and future medical and incidental expenses to be proven at trial;
3. For past and future loss of earnings and/or earning capacity to be proven at trial;
4. For future medical monitoring costs;
5. For special damages to be proven at trial;
6. For punitive and exemplary damages to be proven at trial;
7. For attorney's fees and costs; and
8. For any further legal and equitable relief the Court deems proper.

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 8, 2018

RUTHERFORD LAW

By: _____
MICHELLE M. RUTHERFORD
Attorneys for Plaintiffs

DATED: May 8, 2018

AIDS HEALTHCARE FOUNDATION

By: _____
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