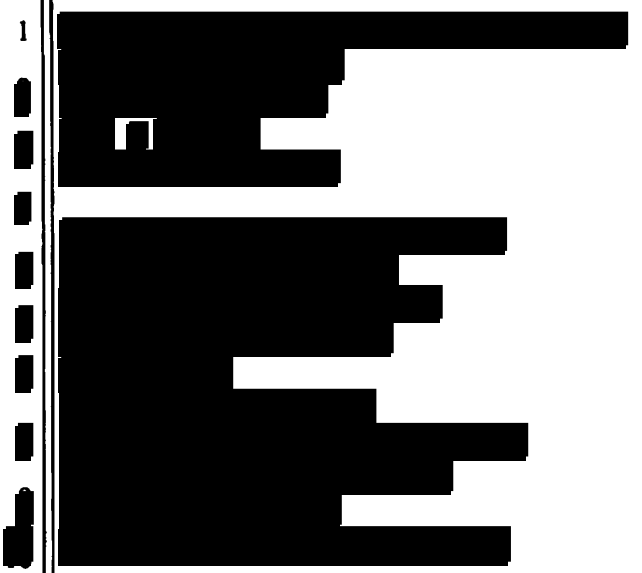

Attorneys for Plaintiffs

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

DEVIN MARTINEZ and RICARDO WOHLER, individually, and on behalf of all others similarly situated,

Plaintiffs,

v.

GILEAD SCIENCES, INC.

Defendant.

Case No. _____

CLASS ACTION COMPLAINT FOR INJUNCTIVE RELIEF AND DAMAGES
Unlimited Civil Action

1. **CALIFORNIA CONSUMER LEGAL REMEDIES ACT [CALIFORNIA CIVIL CODE § 1750, *et seq.*]**
2. **CALIFORNIA'S UNFAIR COMPETITION LAW [CALIFORNIA BUSINESS & PROFESSIONS CODE § 17200 *et seq.*]**

DEMAND FOR JURY TRIAL

Plaintiffs Devin Martinez and Ricardo Wohler ("Plaintiffs"), on behalf of themselves and all others similarly situated, bring this action against Defendant Gilead Sciences, Inc. ("Gilead") to recover monetary damages, injunctive relief, and other remedies for violations of California law. Plaintiffs' allegations as to their own acts are based on their personal knowledge. Plaintiffs' allegations as to all other matters are based on information and belief.

I. INTRODUCTION

Plaintiffs are consumers of Defendant Gilead's tenofovir and tenofovir-based antiviral medications, Viread, Truvada, and Atripla. Plaintiffs were prescribed and 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.

Gilead knew, or should have known, at the time it developed, manufactured, and sold Viread, Truvada, and Atripla 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. As well, at the same time it was promoting TDF as safe and effective, Gilead was researching a safer and more effective prodrug that greatly reduced the risk of toxicity to kidneys and bones.

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

[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.

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. *See generally, In re Gilead Sciences Securities Litigation*, Case No. C-03-499-SI (N.D. Cal).

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 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 as 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.

In addition to these early indications of the potentially permanent or fatal risk of kidney and bone damage, Gilead's own clinical studies into a similar prodrug, tenofovir alafenamide ("TAF"), revealed that TAF was more effective and less toxic to kidneys and bones than TDF.[2]

[2] Gilead's Chairman and CEO John Martin has trumpeted the superior safety of TAF over TDF as a reason for customers to switch. "[TAF] has a superior safety profile compared to TDF. This is important because most newly diagnosed patients will now be treated for decades, and at the same time, many HIV-infected individuals who are in treatment, particularly in the U.S. and Europe, are advancing in age." Q2 2015 Gilead Earnings Call (Jul 29, 2015).

Gilead had been studying TAF before it submitted its first new drug application for TDF to the U.S. Food and Drug Administration ("FDA") in October 2001, under the brand name Viread. And long before it submitted its supplemental new drug applications for Truvada in March 2004 and for Atripla in April 2006.

Indeed, 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, Gilead continued to corner the antiviral market with TDF. Further, by keeping TDF as the focus of its antiviral offerings, Gilead knew it would reap future profits and increased market share when it combined its TDF patent with other patent-protected drugs to create newly-protected combination drugs that would extend the Gilead's monopoly pricing on the sale of TDF.

Gilead's delay in conducting 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, created 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 TAF stayed 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.[3] 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 lead 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 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.*"[4]

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

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

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.

If Gilead's tactics are allowed to continue without sanction, Gilead will continue to harm the public and violate California law. Plaintiffs bring this lawsuit on behalf of themselves and all other California consumers who purchased Gilead's Viread, Truvada, or Atripla from October 26, 2001, through the present, and who were personally or whose physician was exposed to Gilead's misrepresentations about TDF, Viread, Truvada, or Atripla.

II. THE PARTIES

Plaintiff Devin Martinez is a resident of the State of California and the City and County of Los Angeles. Mr. Martinez was prescribed and ingested Gilead's prescription medication Truvada from the time he was diagnosed with HIV in 2013 through approximately 2017.

Plaintiff Ricardo Wohler is a resident of the State of California and the County of Marin. Mr. Wohler was prescribed and ingested Gilead's prescription medication Atripla from approximately 2005 through approximately October 2017.

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 TDF, Viread, 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 Civil Code §§ 1780 and 1781 and Business and Professions Code §§17203 and 17204. 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 Civil Code § 1780(d) because Gilead does business in Los Angeles and a substantial portion of Gilead's misrepresentations, incomplete and misleading warnings, and fraudulent marketing practices occurred in the County of Los Angeles.

IV. CLASS 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 had to be given intravenously so 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.

Because TDF had strong antiviral properties and worked to lower an individual patient's viral load, it became a staple in 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 tenofovir available as a standalone drug product under the brand name Viread, which used TDF as its prodrug formulation, Gilead incorporated tenofovir/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 bioavailability 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. This allowed the toxicity to build overtime, while simultaneously 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, it was only approved for an indication with treatment experienced populations and the FDA required Gilead to study whether it would harm humans.[5] 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 result in kidney or bone toxicities in humans as it had in animal studies. *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

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

in April 2002, Gilead paid doctors to conduct clinical studies of TAF in HIV patients around the country.[6]

After learning that TAF had a higher absorption rate and largely avoided the bone and kidney toxicity associated with TDF, Gilead shelved its development of TAF and instead kept HIV infected patients and their doctors in the dark about the true 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 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 Mispresenting Risks Associated with Viread

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

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[6] 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).

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 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.[7]

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

[7] 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.

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.

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.

g. The Class of Consumers

Plaintiffs bring this class action for damages and other monetary relief on behalf of the following class:

> All persons located within California who were prescribed and ingested Viread, Truvada, or Atripla from October 26, 2001, through the present, who were personally or whose physician was exposed to Gilead's misrepresentations.

The proposed Class is so numerous that individual joinder of all its members is impracticable. Due to the nature of the trade and commerce involved, however, Plaintiffs believe that the total number of Class members is at least in the thousands and members of the Class are numerous and geographically dispersed across California. While the exact number and identities of the Class members are unknown at this time, such information can be ascertained through appropriate investigation and discovery. The disposition of the claims of the Class members in a single class action will provide substantial benefits to all parties and to the Court.

There is a well-defined community of interest in the questions of law and fact involved

affecting the plaintiff class and these common questions predominate over any questions that may affect individual Class members. Common questions of fact and law include, but are not limited to, the following:

a. Whether Gilead falsely represented that Viread, Truvada, and Atripla have benefits which they do not have;

b. Whether Gilead knew that its risk claims were false;

c. Whether Gilead's conduct constitutes a violation of the Consumers Legal Remedies Act (Cal. Civ. Code §§ 1750, et seq.);

d. Whether Defendant's conduct constitutes an unfair, unlawful, and/or fraudulent business practice in violation of California's unfair competition law (Cal. Bus. & Prof. Code §§ 17200, et seq.);

e. Whether Plaintiffs and Class members are entitled to compensatory damages, and if so, the nature of such damages;

f. Whether Plaintiffs and Class members are entitled to restitution; and

g. Whether Plaintiffs and Class members are entitled to injunctive relief.

Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class have been similarly affected by Gilead's common course of conduct since they, or their physicians, all relied on Gilead's representations concerning the risks associated with TDF, Viread, Truvada, and Atripla and prescribed or ingested product based on those representations.

Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs have retained counsel with experience in handling class action litigation. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the Class and have the financial resources to do so.

Plaintiffs and the members of the Class suffered, and will continue to suffer, harm as a result of Gilead's unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the present controversy. Individual joinder of all members of the class is impracticable. Even if individual class members had the resources to

pursue individual litigation, it would be unduly burdensome to the courts in which the individual litigation would proceed. Individual litigation magnifies the delay and expense to all parties in the court system of resolving the controversies engendered by Gilead's common course of conduct. The class action device allows a single court to provide the benefits of unitary adjudication, judicial economy, and the fair and efficient handling of all class members' claims in a single forum. The conduct of this action as a class action conserves the resources of the parties and of the judicial system and protects the rights of the class members. Further, for many, if not most, a class action is the only feasible mechanism that allows an opportunity for legal redress and justice.

Adjudication of individual class members' claims with respect to Defendant would, as a practical matter, be dispositive of the interests of other members not parties to the adjudication and could substantially impair or impede the ability of other class members to protect their interests.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION
VIOLATION OF CALIFORNIA CONSUMER LEGAL REMEDIES ACT (§ 1750)
(By Class against All Defendants)

Plaintiffs fully reallege and incorporate by reference each allegation made above as if fully set forth here.

Plaintiffs have standing to pursue this cause of action because Plaintiffs have suffered injury in fact and have lost money, whether out of pocket, in the form of a copay, or in the form of money paid by an insurer, as a result of Gilead's actions as set forth herein. Specifically, Plaintiffs and/or their physicians prescribed and/or ingested Viread, Truvada, and Atripla in reliance on Gilead's labeling and representations of TDF's safety.

Gilead has engaged in and continues to engage in business practices in violation of California Civil Code §§ 1750, *et seq.* (the "Consumers Legal Remedies Act" or "CLRA") by making false and unsubstantiated representations concerning the benefits and risk associated with TDF. Gilead's business practices are misleading and/or likely to mislead consumers and should be enjoined.

Gilead has engaged in deceptive acts or practices intended to result in the sale of Viread, Truvada, and Atripla in violation of Civil Code § 1770. Gilead knew and/or should have known that its representations of fact concerning the benefits and risks of the products were material and likely to mislead the consuming public.

Gilead affirmatively misrepresented that Viread, Truvada, and Atripla had certain benefits which they do not have. That is Gilead misrepresented the drugs as safe, with limited risk of bone or kidney damage, and without a need for monitoring of early signs of toxicity.

Gilead's conduct alleged herein violates the Consumers Legal Remedies Act, including but not limited to, the following provisions:

(1) misrepresenting the source, sponsorship, approval or certification of goods or services in violation of Civil Code § 1770(a)(2);

(2) misrepresenting the affiliation, connection, or association with, or certification by another in violation of Civil Code § 1770(a)(3);

(3) misrepresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have in violation of Civil Code § 1770(a)(5); and/or

(4) advertising goods or services with intent not to sell them as advertised in violation of Civil Code § 1770(a)(9).

As a direct and proximate result of Gilead's conduct, as set forth herein, Gilead has received ill-gotten gains and/or profits, including but not limited to, money. Therefore, Gilead has been unjustly enriched.

There is no other adequate remedy at law, and Plaintiffs and Class members will suffer irreparable harm unless Gilead's conduct is enjoined.

Concurrently herewith, Plaintiffs' counsel mailed to Defendant, by certified mail, return receipt requested, the written notice required by Civil Code Section 1782(a) on May 8, 2018. A Copy of the letter is attached hereto as Exhibit A.

The venue declaration required by Civil Code § 1780(d) is attached hereto as Exhibit B.

Gilead's wrongful business practices constituted, and still constitute, a continuing course

of conduct in violation of the Consumers Legal Remedies Act since Gilead is still representing that Viread, Truvada, and Atripla have characteristics, uses, benefits, and abilities that are false and misleading, and have injured Plaintiffs and the Class.

SECOND CAUSE OF ACTION
VIOLATION OF CALIFORNIA BUSINESS AND PROFESSIONS CODE (§ 17500)
(By Plaintiffs and Class against All Defendants)

Plaintiffs fully reallege and incorporate by reference each allegation made above as if fully set forth here.

Plaintiffs have standing to pursue this cause of action because Plaintiffs have suffered injury in fact and have lost money as a result of Defendant's actions as set forth herein.

Specifically, Plaintiffs were prescribed and ingested Viread, Truvada, and/or Atripla in reliance on Gilead's marketing claims as described above. Gilead has engaged in false advertising as it has disseminated false and/or misleading representations about TDF, Viread, Truvada, and Atripla.

Gilead knew or should have known that its representations were false and/or misleading. During the Class Period, Gilead engaged in false advertising in violation of Cal. Bus. & Prof. Code §§ 17200, 17500, *et seq.* by misrepresenting in its advertising and marketing of the product to Plaintiffs, Class members, their physicians, and the consuming public the benefits and risks of TDF, Viread, Truvada, and Atripla.

Each of the misrepresentations alleged in this Complaint was false and misleading regarding the benefits and risks of TDF, Viread, Truvada, and Atripla. By disseminating and publishing these assertions in connection with the sale of the product, Gilead has engaged in and continues to engage in false advertising in violation of California Bus. & Prof. Code §§ 17200, 17500, *et seq.*

As a direct and proximate result of Gilead's conduct, as set forth herein, Gilead has received ill-gotten gains and/or profits, including but not limited to, money. Therefore, Gilead has been unjustly enriched. Pursuant to Cal. Bus. & Prof. Code § 17535, Plaintiffs request restitution and restitutionary disgorgement for all sums obtained in violation of Cal. Bus. & Prof. Code §§ 17200, 17500, *et seq.*

Plaintiffs seek injunctive relief, restitution, and restitutionary disgorgement of Gilead's ill-gotten gains as specifically provided in Cal. Bus. & Prof. Code § 17535. Plaintiffs and Class members seek to enjoin Gilead from engaging in these wrongful practices in the future. There is no other adequate remedy at law and if an injunction is not ordered, Plaintiffs and the Class will suffer irreparable harm and/or injury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and members of the Class request that the Court enter an order or judgment against Defendant, and each of them, as follows:

i. For an order certifying the Class, appointing Plaintiffs and Plaintiffs' counsel to represent the Class, and notice to the Class to be paid by Defendant;

ii. For damages suffered by Plaintiffs and Class members;

iii. For restitution to Plaintiffs and Class members of all monies wrongfully obtained by Defendant;

iv. For an injunction ordering Defendant to cease and desist from engaging in the unfair, unlawful, and/or fraudulent practices alleged in the Complaint;

v. For both pre-judgment and post-judgment interest at the maximum allowable rate on any amounts awarded;

vi. For Plaintiffs' costs of the proceedings herein;

vii. For reasonable attorneys' fees as allowed by statute; and

viii. For any and all such other and further relief that this Court may deem just and proper.

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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

[redacted]

Attorneys for Class Plaintiffs

EXHIBIT A

[redacted]

[redacted]

May 8, 2018

VIA CERTIFIED UNITED STATES MAIL

Gilead Sciences, Inc.
c/o General Counsel
333 Lakeside Drive
Foster City, CA 994404

Re: *Notice of Violation of California Consumer Legal Remedies Act*

To Gilead Sciences, Inc.:

Together with my co-counsel at AIDS Healthcare Foundation, I represent Devin Martinez and Ricardo Wohler, on behalf of themselves and all other similarly-situated California consumers (collectively, the Class). Pursuant to the California Consumer Legal Remedies Act, (CLRA), California Civil Code section 1750, *et seq.*, and as required by section 1782, Mr. Martinez, Mr. Wohler, and the Class hereby notify you that Gilead Sciences, Inc. (Gilead) that it is alleged to have violated the CLRA by warranting, marketing, advertising, and selling Viread, Truvada, and Atripla, without sufficient warnings of the risks associated with them and by warranting that they were safe and effective. The violations are detailed further below. As required by subsection (b), this letter demands that you remedy these violations within thirty (30) calendar days from your receipt of this letter.

Mr. Martinez is a resident of the State of California and the City and County of Los Angeles. Mr. Martinez was prescribed and ingested Gilead's prescription medication Truvada from the time he was diagnosed with HIV in May 2013 through May 2017.

Mr. Wohler is a resident of the State of California and the County of Marin. Mr. Wohler was prescribed and ingested Gilead's prescription medication Atripla from 2005 through October 2017.

Gilead's violations of the CLRA have caused injury and financial consequences for our clients. Gilead knew of the risks of toxicity and bone and kidney damage and concealed them from consumers and the public in a manner that violates the CLRA.

California Civil code section 1770 (a) provides in relevant part:

> "The following unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or that results in the sale or lease of goods or services to any consumer are unlawful:

(2) Misrepresenting the source, sponsorship, approval, or certification of goods or services.

(3) Misrepresenting the affiliation, connection, or association with, or certification by, another....

(5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have....

(9) Advertising goods or services with intent not to sell them as advertised."

Gilead's misrepresentations and its active concealment of and failure to disclose the risks in warranting, marketing, advertising, and selling of Viread, Truvada, and Atripla constitute the violations of the CLRA.

Gilead Sciences, Inc., has violated these provisions in the following ways:

- By making false and unsubstantiated representations concerning the benefits and risks associated with TDF.
- As early as 2001, Gilead knew but failed to disclose that TDF had significant risk for toxicity and bone and kidney damage.
- Gilead failed to warn about the full extent and significance of these risks for all patients, not just patients with pre-existing kidney or bone issues.
- Gilead's misrepresentations regarding the risks and benefits associated with TDF have were intended to and have resulted in the sale of Viread, Truvada, and Atripla in violation of Civil Code § 1770.
- Gilead knew and/or should have known that its representations of fact concerning the benefits and risks of the products were material and likely to mislead the consuming public.
- Gilead affirmatively misrepresented that Viread, Truvada, and Atripla had certain benefits which they do not have.
- Gilead misrepresented the drugs as safe, with limited risk of bone or kidney damage, and without a need for monitoring of early signs of toxicity.

Pursuant to section 1782, subdivision (a)(2), and based on the forgoing, we hereby demand that within thirty (30) days of receiving this letter Gilead: i) agree to refund Mr. Martinez, Mr. Wohler, and the Class, for all monies paid by them or on their behalf for their purchase of Viread, Truvada, and/or Atripla at the market rate that was charged to them or their insurance company; and ii) correct the warnings on all the prescribing information inserts and patient information sheets for all three products to properly warn of the risk of toxicity and damage to bones and kidneys. These warnings should include, but not be limited to, a warning

that there is a risk of toxicity and/or bone and kidney damage to all patients, including those patients without pre-existing bone or kidney issues. These warnings should include, but not be limited to, informing prescribing physicians that all patients taking Viread, Truvada, and/or Atripla should be monitored for proper kidney function and bone mineral density.

Please be advised that should Gilead refuse this demand, Mr. Martinez, Mr. Wohler, and the Class will seek monetary damages for themselves and the Class, as well as an award of injunctive relief, restitution, punitive damages, attorney's fees and costs and any other relief the court deems proper.

If you have any questions regarding this notice and demand, feel free to contact me at (415) 794-5639.

[redacted]

EXHIBIT B

DECLARATION OF DEVIN MARTINEZ

I, Devin Martinez, hereby declare as follows:

1. I am a Plaintiff in the lawsuit against Gilead Sciences, Inc. and specifically to the First Cause of Action for Violation of the California Consumer Legal Remedies Act.
2. I am a competent adult, over eighteen years of age, and at all times material to this complaint I have been a citizen of the United States, residing in Los Angeles, California. I make this affidavit as required by California Civil Code § 1780(d).
3. The Complaint in this action is filed in the proper place for trial because Gilead Sciences, Inc. does business in Los Angeles County, where a substantial portion of the acts, omissions, and transactions in the Complaint arose.

I declare under penalty of perjury under the laws of the United States that the foregoing is true to the best of my knowledge.

Executed this 7th day of May 2018 in Las Vegas, Nevada.

[redacted]