1. Lead Plaintiffs Trent St. Clare and Terry Johnson (“Plaintiffs”) bring this federal securities class action individually, and on behalf of a proposed class (the “Class”) of all purchasers of the publicly traded securities of Gilead (NASDAQ: GILD) between July 14, 2003 and October 28, 2003, inclusive (the “Class Period”), against Gilead Sciences, Inc. (“Gilead” or the “Company”) and certain of its top officers seeking remedies under the Securities Exchange Act of 1934 (the “Exchange Act”).
2. Gilead, based in Foster City, California, is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical treatments for life-threatening diseases. According to Gilead’s Forms 10-Q for the periods ending June 30, 2003 and September 30, 2003, the Company has six approved commercial products, including Viread, an antiretroviral agent used in combination with other drugs for the treatment of HIV infection. Viread product sales are approximately 65% of Gilead’s total revenues.

3. As stated in Gilead’s Form 10-K for the period ending December 31, 2002 (“2002 10-K”), filed with the United States Securities and Exchange Commission (“SEC”) on March 14, 2003, Gilead’s commercial teams “promote Viread ... through direct field contact with physicians, hospitals, clinics and other healthcare providers who are involved in the treatment of patients with HIV.”

4. Throughout the Class Period, Defendants knowingly and affirmatively misrepresented the most important measurement of Gilead’s performance and prospects to the investing public: the nature and cause of its increased sales of Viread. Wall Street analysts looked to sales of Viread, Gilead’s most important and most promoted drug, to gauge whether the Company’s business was on track and growing. If Gilead failed to publicly report healthy, growing Viread sales, its stock price would be greatly diminished.

5. Indeed, in an October 28, 2003 press release, Defendant and CEO John C. Martin (“Martin”) addressed Gilead’s need to obtain “higher prescription volumes” for Viread and identified the “important demand indicators” for Viread as being “new and total prescriptions.” Thus, according to the 2002 10-K, Gilead had to “maintain and expand its position in the marketplace” (2002 10-K at 24) in the following areas: “efficacy; safety; tolerability; acceptance by doctors; patient compliance; patent protection; ease of use; price; insurance and other reimbursement coverage; distribution; marketing; and adaptability to various modes of dosing.” 2002 10-K at 18.

6. In an October 27, 2003 Forbes article, Defendant Martin acknowledged that in order for Gilead to reach its goal of increasing new and total prescriptions, it had to convince physicians to switch patients from a competitor’s drugs to Gilead’s Viread drug regimen.
According to the article, Defendant Martin “concedes this is driven by marketing: ‘The AIDS market is driven by data.’” Thus, according to the author, “Gilead, lacking a big ad budget, woos doctors by putting out a slew of data showing Viread to be more effective than [competitor drugs], with fewer nasty side effects.”

7. In accordance with their business plan, Defendants made certain that Gilead reported extremely impressive Viread sales results during the Class Period. Unfortunately for investors, these results were attained through: (1) Defendants’ campaign of false and misleading promotional activities for Viread found to be in violation of the Federal Food, Drug and Cosmetic Act and its implementing regulations by the U.S. Food and Drug Administration (“FDA”); and (2) wholesaler overstocking of massive amounts of Viread in anticipation of an announced price increase. To successfully implement their campaign of false and misleading promotional activities, both prior to and during the Class Period, Defendants engaged in a systematic plan to market Viread using clinical studies and other materials that had not received FDA approval and by inducing Gilead sales and marketing representatives to make false and misleading statements concerning Viread’s safety and efficacy to physicians, medical professionals and others. Such tactics are generally referred to as “off-label marketing.” In doing so, Defendants minimized important risk information regarding Viread, promoted Viread on the basis of unproven and untested theories, and “broadened the indication” for prescribing Viread to patients in violation of FDA regulations by, among other things, indicating it could treat other diseases or infections, even though the FDA never approved such treatment. On two occasions, the FDA ordered Gilead to cease and desist this practice. Gilead blatantly ignored the FDA’s first warning (in 2002) and thus received the second, more dire, warning in July 2003 (during the Class Period). Defendants’ false, misleading, and illegal promotional practices resulted in increased sales of Viread during, at least, the Class Period.

8. Indeed, Gilead’s off-label and illegal promotional practices led to increased prescriptions which enabled Defendants to create the false and misleading impression that demand for Viread was much stronger than it actually was during the Class Period. As
acknowledged by Defendants, increased Viread prescriptions were the primary indicator of strong Viread demand.

9. In June 2003, Gilead announced a price increase for Viread, enticing drug wholesalers to stock up on massive amounts of Viread in anticipation of the price increase and in reliance on Gilead’s inflated sales. As with Gilead’s improper promotional scheme, wholesaler overstocking created the appearance of increased sales.

10. However, demand for Viread was not nearly as strong as Defendants led the market to believe. In reality, the increased Viread prescriptions were driven, at all relevant times, by Defendants’ false and misleading Viread promotional campaign in violation of federal law. Based on this fraud, Defendants released false and misleading financial and operational results in order to sustain Gilead’s high stock price at the expense of Gilead’s investors, the market, and, importantly, the patients who depend on Viread to prolong their lives.

11. As a result, at the beginning of the Class Period, Gilead announced that overall sales doubled during Second Quarter 2003, year-over-year, largely on the strength of Viread sales. The news caused Gilead’s stock price to rise $7.97 in one day, to a near-record high of $67.25.

12. However, certain securities analysts questioned whether the apparent strong demand for Viread resulted from wholesalers stocking up on the drug ahead of a price increase announced by Gilead in June 2003. The analysts’ concern was that in future quarters demand for Viread would be met by inventory stocked by the wholesalers, rather than by new sales.

13. Indeed, in order to sell their stock at artificially inflated prices and to sustain the false and misleading impression that demand for Viread was strong, Defendants unequivocally rebutted the analysts’ concerns. Defendants represented that the strong Second Quarter 2003 Viread sales were due to “an increase in prescriptions, not inventory stocking” and that “increased stocking by U.S. wholesalers accounted for $25-$30 million of Viread sales” (rather than the much larger amount Defendants disclosed a few months later). Defendants’
unequivocal rebuttal had the intended effect of artificially maintaining Gilead’s stock price long enough for Defendants to dump their Gilead shares on an unsuspecting market.

14. In just twenty-four days (between August 5, 2003 and August 29, 2003), Defendants sold in excess of 300,000 shares of Gilead stock at artificially inflated prices, reaping gross proceeds in excess of $20 million. This was the first and only time when all of the Defendants sold their stock during one coordinated time period. Notably, Defendants’ selling spree took place just days after they had received FDA notification (sent to Gilead, c/o Defendant Martin on July 29, 2003) – for the second time since the launching of Viread – that their Viread promotional campaign and off-label marketing practices violated federal laws.

15. Just as some Wall Street analysts had suspected, and despite Gilead’s prior denials, at the end of the Class Period Defendants announced that sales of Viread in Third Quarter 2003 would be materially less than previously indicated. According to Defendants’ press release, wholesaler overstocking of Viread accounted for $33 million to $37 million in Second Quarter 2003 sales, not $25 million to $30 million as they had previously represented. As a result, end-user demand for Viread in Third Quarter 2003 would be met by an equal amount of sales from wholesalers’ existing inventory rather than by new sales. In short, demand for Viread was not as strong as Defendants had led the market to believe.

16. In reaction to Defendants’ belated admission, the price of Gilead stock plummeted, falling $7.46 in one day, from $59.46 per share on October 28, 2003, to $52 per share on October 29, 2003.

17. Nevertheless, while disclosing their reliance on wholesaler overstocking, Defendants failed to disclose that the amount of Viread sales and prescriptions was also due to their intentional, improper, and illegal marketing and promotional campaign. As a result, the price of Gilead stock was overstated throughout the Class Period.

JURISDICTION AND VENUE

18. Plaintiffs bring this action pursuant to §§ 10(b) and 20(a) of the Securities Exchange Act, of 1934 (the “Act”) (15 U.S.C. §§78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).
19. This Court has jurisdiction over the subject matter of this action pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1331.

20. Venue is proper in this District pursuant to §27 of the Exchange Act, 15 U.S.C. §78aa and 28 U.S.C. §1391(b). At all times relevant to this action, Gilead maintained its principal place of business in this District and many of the acts and transactions alleged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.

21. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications, and the facilities of the national securities markets.

THE PARTIES

Plaintiffs

22. Plaintiffs Trent St. Clare and Terry Johnson purchased Gilead securities on the open market during the Class Period as set forth in their certifications previously filed with the Court. The Court’s January 30, 2004 Order appointed St. Clare and Johnson as Lead Plaintiffs in this consolidated action.

Defendants

23. Defendant Gilead, a Delaware corporation, maintains its principal place of business at 333 Lakeside Drive, Foster City, California 94404. Gilead is a biopharmaceutical company that discovers, develops, and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases worldwide. The Company has six commercial products including Viread, an antiretroviral agent used in combination with other drugs for the treatment of HIV infection.

24. During the Class Period, Defendant Martin was the Company’s President and Chief Executive Officer.

25. During the Class Period, Defendant John F. Milligan (“Milligan”) was the Company’s Chief Financial Officer and Senior Vice-President.
26. During the Class Period, Defendant Mark L. Perry ("Perry") was the Company’s Executive Vice-President, Operations.

27. During the Class Period, Defendant Norbert W. Bischofberger ("Bischofberger") was the Company’s Executive Vice-President, Research and Development.

28. During the Class Period, Defendant Anthony Carraciolo ("Carraciolo") was the Company’s Vice-President.

29. During the Class Period, Defendant William A. Lee ("Lee") was the Company’s Senior Vice-President, Research.

30. Martin, Milligan, Perry, Bischofberger, Carraciolo, and Lee (collectively the "Individual Defendants") were privy to non-public information concerning Gilead’s business, finances, sales, products, product marketing and promotion, and present and future business prospects via access to internal corporate documents, conversations, and connections with other corporate officers and employees, attendance at sales management and Board of Directors meetings and committees thereof, and via reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew or with deliberate recklessness disregarded the fact that adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public. Except to the extent set forth in this Complaint as provided by confidential witnesses who are primarily former Gilead employees, Plaintiffs and other members of the Class had no access to such information, which was, and remains solely under the control of Defendants. The Individual Defendants were involved in drafting, producing, reviewing, and/or disseminating the materially false and misleading statements complained of herein. The Individual Defendants were aware (or disregarded with deliberate recklessness) that materially false and misleading statements were being issued regarding the Company and nevertheless approved, ratified, and/or failed to correct those statements, in violation of the federal securities laws.

31. Throughout the Class Period, the Individual Defendants were able to, and did, control the contents of the Company’s SEC filings, reports, press releases, and other public
statements. The Individual Defendants were provided with copies of, reviewed and approved, and/or signed such filings, reports, releases, and other statements prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. The Individual Defendants also were able to, and did, directly or indirectly, control the conduct of Gilead’s business, the information contained in its filings with the SEC, and its public statements. Moreover, the Individual Defendants made or directed the making of affirmative statements to securities analysts and the investing public at large, and participated in meetings and discussions concerning such statements. Because of their positions and access to material non-public information available to them but not the public, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations that were being made were then false and misleading. As a result, each of the Individual Defendants is responsible for the accuracy of Gilead’s corporate releases detailed herein as “group-published” information and is therefore responsible and liable for the representations contained therein.

32. Each of the Defendants is liable as a primary violator in making false and misleading statements, and for participating in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Gilead securities during the Class Period. All of the Defendants had motives to pursue a fraudulent scheme in furtherance of their common goal, *i.e.*, inflating the trading price of Gilead securities by making false and misleading statements and concealing material adverse information. The fraudulent scheme and course of business was designed to and did: (i) deceive the investing public, including Plaintiffs and other Class members; (ii) artificially inflate the price of Gilead securities during the Class Period; (iii) cause Plaintiffs and other members of the Class to purchase Gilead securities at inflated prices; and (iv) allow Gilead to conceal and cover up the true financial condition of Gilead to the detriment of its investors, but to the financial benefit of the Individual Defendants.

**CLASS ACTION ALLEGATIONS**

33. Plaintiffs bring this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of the Class, consisting of all those who purchased the
securities of Gilead during the Class Period. Excluded from the Class are Defendants, the
officers and directors of the Company, members of their immediate families and their legal
representatives, heirs, successors, or assigns and any entity in which Defendants have or had a
controlling interest.

34. Because Gilead has millions of shares of stock outstanding, and because the
Company’s shares were actively traded, members of the Class are so numerous that joinder of
all members is impracticable. As of February 27, 2004, Gilead had over 213 million shares
outstanding. While the exact number of Class members can only be determined by appropriate
discovery, Plaintiffs believe that Class members number at least in the thousands and that they
are geographically dispersed.

35. Plaintiffs’ claims are typical of the claims of the members of the Class, because
Plaintiffs and all of the Class members sustained damages arising out of Defendants’ wrongful
conduct complained of herein.

36. Plaintiffs will fairly and adequately protect the interests of the Class members
and have retained counsel experienced and competent in class actions and securities litigation.
Plaintiffs have no interests that are contrary to or in conflict with the members of the Class they
seek to represent.

37. A class action is superior to all other available methods for the fair and efficient
adjudication of this controversy, since joinder of all members is impracticable. Furthermore, as
the damages suffered by individual members of the Class may be relatively small, the expense
and burden of individual litigation make it impossible for the members of the Class to
individually redress the wrongs done to them. There will be no difficulty in the management of
this action as a class action.

38. Questions of law and fact common to the members of the Class predominate
over any questions that may affect only individual members, in that Defendants have acted on
grounds generally applicable to the entire Class. Among the questions of law and fact common
to the Class are:

(a) whether Defendants violated the federal securities laws as alleged herein;
whether Defendants’ publicly disseminated press releases and statements during the Class Period omitted and/or misrepresented material facts;

(c) whether Defendants breached any duty to convey material facts or to correct material acts previously disseminated;

(d) whether Defendants participated in and pursued the fraudulent scheme or course of business complained of;

(e) whether Defendants acted willfully, with knowledge or deliberate recklessness, in omitting and/or misrepresenting material facts;

(f) whether the market prices of Gilead securities during the Class Period were artificially inflated due to the material nondisclosures and/or misrepresentations complained of herein; and

(g) whether the members of the Class have sustained damages and, if so, what is the appropriate measure of damages.

CONFIDENTIAL WITNESSES

39. Plaintiffs’ allegations herein, concerning the falsity of Defendants’ statements and the scienter of the Individual Defendants, are based upon, in part, interviews with former Gilead employees, including former members of the Company’s sales and marketing staff. These witnesses, who spoke to Plaintiffs’ counsel on a confidential basis, are referred to herein as Confidential Witnesses (hereinafter, “CW__”) numbers 1 and 2.

40. CW1 and CW2 are both former Gilead Therapeutic Specialists (drug salespeople). In addition, CW1 was a member of Gilead’s Field Marketing Advisory Committee, an elite group of Gilead employees responsible for monitoring and shaping Gilead’s marketing efforts and advising Gilead management of the progress of those efforts. The positions that CW1 and CW2 held at Gilead permitted them to have direct access to the information provided by each, as described below.

41. CW1 worked as a Gilead Therapeutic Specialist from 2001 until approximately May 2003. As a Therapeutic Specialist, CW1 was responsible for promoting, marketing, and selling Gilead products, namely Viread, and regularly had contact with and exposure to...
numerous Gilead executives and Regional Directors, including the Individual Defendants (with
the exception of Carraciolo). CW1’s territory covered the Indiana, Illinois, and Michigan
markets. In the course of his or her regular duties, CW1 worked with a variety of healthcare
professionals, including physicians, nurses, social workers, and patients. In addition, over the
course of CW1’s employment with Gilead, CW1 attended and participated in numerous
national and regional Gilead meetings wherein Gilead executives specifically discussed the
promotion of Viread. At these meetings, as well as at other times, Gilead provided CW1 with
detailed information on Viread and told CW1 to use that information to aggressively promote
and sell Viread. Among the information provided, however, was information not approved by
the FDA for use in marketing and promoting Viread. Gilead executives provided this off-label
information despite knowing that off-label marketing violated FDA rules and regulations.
Further, at various times during CW1’s employment with Gilead, Gilead executives
specifically instructed CW1 to teach and train other members of Gilead’s sales and marketing
staff how to improperly and illegally use off-label information to market Viread.

42. Prior to the Class Period, CW1 was a member of Gilead’s Field Marketing
Advisory Committee, a select committee of Gilead sales and marketing staff that periodically
met to discuss theories and strategies for marketing and selling Viread. Members of Gilead’s
sales and marketing staff from various regions of the country, as well as high-ranking Gilead
officers and executives, including, but not limited to, Michael Inouye (“Inouye”), Gilead’s
Senior Vice-President of Commercial Operations, James Meyers (“Meyers”), Gilead’s Vice-
President of U.S. Sales, and various heads of marketing, such as Debbie Fletcher (“Fletcher”)
and Sheryl Meredith (“Meredith”) attended the Field Marketing Advisory Committee meetings.

43. During the course of his or her employment, CW1 reported directly to Gary
DelloStritto (“DelloStritto”), Gilead’s Regional Director for the Mid-West. In turn,
DelloStritto reported to Meyers, Gilead’s Vice-President of U.S. Sales, who reported to Shay
Weisbrich (“Weisbrich”), Gilead’s Vice-President of Sales and Marketing. Both Meyers and
Weisbrich were members of Gilead’s Senior Management Team. Ultimately, Weisbrich was
responsible to Inouye, Gilead’s Senior Vice-President of Commercial Operations and a member
of the Executive Committee. Lastly, Inouye reported to the Individual Defendants, including Defendant Martin, and the Board of Directors.

44. CW2 worked as a Gilead Therapeutic Specialist from July 2000 until approximately February 2004. As a Therapeutic Specialist, CW2 was responsible for promoting, marketing, and selling Gilead products, namely Viread, and worked with a variety of healthcare professionals, including physicians, nurses, social workers, and patients in a manner similar to CW1. CW2 was, at various times throughout his tenure, responsible for covering the Georgia, South Carolina, and Alabama markets.

45. CW2 began his or her career at Gilead in the South sales region. During that time, CW2 reported to Bill Rich ("Rich"), Gilead's Regional Director for the South. In turn, Rich reported to Meyers, who reported to Inouye. Lastly, Inouye reported to the Individual Defendants, including Defendant Martin, and the Board of Directors.

46. During CW2's employment, CW2 also was a member of Gilead's Dallas region and Southeast regions. While a member of Gilead's Dallas and Southeast regions, CW2 reported to Kirk Kaiser ("Kaiser"), a Gilead Regional Director, and later to Charles Packard ("Packard"), another Gilead Regional Director. Kaiser and Packard reported to Rich. Rich, in turn, reported to Meyers. Finally, Meyers reported, at various times, to either Weisbrich or Fletcher (who replaced Weisbrich) and Inouye.

47. CW2 participated in pre-launch training for Viread, including, but not limited to, Gilead seminars and Gilead home-study materials. According to CW2, during the pre-launch period, Gilead was unsure whether the FDA would approve Viread and, if so, whether the approved indication(s) for Viread would be broad or limited. CW2 explained that if the FDA approved Viread it could be for the use of Viread over a spectrum of indications from a "salvage" indication to an "experienced" indication to a "naïve" indication. A "salvage" indication would limit Viread's use to patients with long-term HIV infection. An "experienced" indication would allow Viread's use by patients treated with other HIV drugs. Finally, a "naïve" indication would mean that Viread could be used by patients recently infected with HIV but not exposed to a diverse treatment regimen. The "naïve" indication is
broader than the “experienced” indication and much broader than the “salvage” indication. Gilead wanted a “naïve” indication which would allow for much higher levels of Viread sales. CW2 estimates that seventy percent (70%) of AIDS drugs are sold to “naïve” and “experienced” patients, while only thirty percent (30%) are sold to “salvage” patients.

48. While awaiting FDA approval, and while not knowing what indication Viread might receive, Gilead taught its sales staff to prepare to market Viread as though it had been approved with the broadest possible indication. According to CW2, Gilead’s earliest plans included a scheme to market Viread to “naïve” and “experienced” HIV patients regardless of the breadth of FDA approval.

49. Over the course of his or her employment with Gilead, CW2, like CW1, attended and participated in numerous national and regional Gilead meetings wherein Gilead executives specifically discussed the promotion of Viread. At these meetings, as well as at other times, Gilead executives provided CW2 with detailed off-label information for Viread and told CW2, both overtly and covertly, to use that information to aggressively promote and sell Viread despite the fact that those executives knew that such off-label marketing violated the FDA’s rules and regulations.

50. Nevertheless, despite his or her superiors’ pressure to market Viread utilizing off-label materials, CW2 refused. Ultimately, CW2 terminated his or her employment with Gilead rather than follow these questionable directives to use off-label materials.

FACTUAL DETAIL UNDERMINING THE TRUTH OF DEFENDANTS’ CLASS PERIOD REPRESENTATIONS

A. Gilead’s Fraudulent Off-Label Marketing Campaign

FDA Prohibitions

51. The Federal Food, Drug, and Cosmetic Act, and its implementing regulations, 21 U.S.C. §301, et seq., set forth the manner in which a pharmaceutical manufacturer is permitted to market and promote its products. According to these guidelines, a pharmaceutical manufacturer may only promote an FDA approved drug consistent with the contents of the drug’s official package labeling (the “Package Labeling”). See 21 C.F.R. §202.1. To ensure
that pharmaceutical companies comply with these rules, the FDA monitors and enforces the Federal Food, Drug, and Cosmetic Act through its Division of Drug Marketing, Advertising, and Communications (the “DDMAC”).

52. In their public statements, Defendants emphasized that their business plan placed great importance on their careful compliance with these federal and state regulations. For example, in Gilead’s 2002 10-K, Defendants stated,

In the U.S., drugs are subject to rigorous FDA regulation. The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. ... We are required to demonstrate the safety and effectiveness of products we develop in each intended use through extensive preclinical studies and clinical trials in order to obtain regulatory approval of these products.

53. Based upon FDA rules and regulations, each of Gilead’s FDA-approved drugs is accompanied by prescribing information provided to doctors prescribing and patients using the drug (the “Prescribing Information”). The FDA approves every word of the Prescribing Information, which is part of the Package Labeling. The Package Labeling thus provides information about the drug, its approved and intended uses, and a description of its side effects. The Package Labeling is vital to a physician’s determination of whether to prescribe the drug. Indeed, the Physician’s Desk Reference (“PDR”), the standard guide to prescription drugs, reproduces the FDA approved prescribing information and labeling to allow physicians, pharmacists, and other medical professionals to correctly use prescription drugs to treat their patients.

54. Because the information contained in the Package Labeling is based upon medical studies and scientific data submitted to and approved by the FDA, it is used by physicians to determine whether a drug can be safely used and tolerated by their patients. The FDA prohibits pharmaceutical manufacturers’ sales and marketing representatives from promoting prescription drugs with information not found in the Package Labeling. As such, use of non-FDA approved materials is referred to as “off-label” marketing.

55. For example, it would be considered off-label for a company to market a FDA-approved HIV/AIDS drug as also being effective for fighting Hepatitis B infection (which
Gilead did with Viread) if such use of the drug had not been reviewed and approved by the FDA and included in the Package Labeling. So long as the Package Labeling lacks information regarding the HIV drug’s ability to fight Hepatitis B infection, the company’s sales representatives are not permitted to speak about this to their customers.

56. The only exception to this rule is if a physician or other medical professional specifically requests such information first, via a signed written form. For example, a physician may be treating a patient who has both HIV and Hepatitis B infection. While treating the patient, the physician may notice that the patient’s HIV medication appears to positively impact the patient’s Hepatitis B infection symptoms. In such a situation, if the doctor submits a written request to the drug manufacturer, typically by utilizing a Gilead inquiry form (the “Inquiry Form”), he or she may see the results of studies which detail the drug’s interaction with Hepatitis B infection, even if those results are not FDA approved or found in the Package Labeling. See Exhibit A attached hereto (a true and correct copy of a Gilead Inquiry Form).

57. Without such a request it is a direct violation of FDA rules and regulations for a drug company to provide its customers with off-label information. And yet, according to the Confidential Witnesses, Defendants encouraged and expected Gilead’s sales and marketing staff to do exactly that, and then – after the fact – obtain an Inquiry Form to create the appearance of propriety.

58. Moreover, Defendants trained Gilead’s sales force to purposely misuse off-label information in order to boost sales and gain an advantage over competitors.

59. While companies are permitted to promote their products with information found in the Package Labeling, Gilead, as part of its scheme to artificially boost Viread sales, repeatedly exceeded this recognized limitation set by the FDA to promote Viread. Specifically, since prior to the launch of Viread, Gilead implemented a scheme to promote and market Viread with off-label, false, and misleading statements in violation of the Federal Food, Drug, and Cosmetic Act. In order to gain market share and increase sales, Gilead officers, executives and clinical personnel, with the express knowledge and approval of the Individual Defendants, routinely and consistently provided Gilead’s sales and marketing team with off-label
information and encouraged, expected, and directed them to use it to sell Viread even without
the written request of a medical professional. Gilead’s sales and marketing strategies, as well
as its corporate culture, rested heavily on selling Viread by way of off-label, unapproved
information.

60. According to CW1, in an effort to win FDA approval for Viread, Gilead
submitted to the FDA a book of Viread clinical data and information, entitled the FDA
Advisory Committee Briefing Document (the “FDA Briefing Document”). See Exhibit B
attached hereto (a true and correct copy of the FDA Briefing Document). The FDA did not
include all of the information found in the FDA Briefing Document in Viread’s Package
Labeling. For example, the FDA Briefing Document contained information regarding Viread’s
impact on bone density and the incidence of bone fracture resulting from Viread use. Because
the FDA withheld such information from the Package Labeling, Gilead’s sales team was
prohibited from marketing Viread as being superior to other HIV drugs with regard to bone
density issues.

61. CW1 confirmed that Gilead submitted the FDA Briefing Document to the FDA
because, in September 2001, while attending a company-wide national meeting in Miami,
Florida (the “Miami National Meeting”) CW1 and other members of Gilead’s sales and
marketing team viewed, via teleconference, Gilead’s executives and clinical researchers
presentation to the FDA Advisory Committee in Washington, D.C. In addition, while at the
Miami National Meeting, CW2 confirmed the substance of the materials Gilead’s executives
covered during the teleconference.

62. According to both CW1 and CW2, among those present at the Washington, D.C.
FDA presentation were Defendants Martin, Perry, Lee, and Milligan. All in attendance at the
FDA briefing were aware that Gilead’s sales and marketing staff was watching the presentation
via teleconference at the Miami National Meeting. The Miami National Meeting
teleconference was attended by, among others, Meyers, Weisbrich, and Fletcher. According to
CW1 and CW2, the purpose of the teleconference was to allow Gilead’s salespeople and
marketing department to become familiar with the FDA Briefing Document and related
materials in order to market Viread, regardless of the FDA’s approval and indication assigned to Viread.

63. After making their presentation to the FDA, Gilead’s officers, executives, and clinical personnel, including Inouye and Defendants Martin, Milligan, Perry, and Bischofberger traveled to the Miami National Meeting already in progress. CW1 and CW2 specifically recall that, while at the Miami National Meeting, Gilead representatives provided them and other Gilead sales and marketing staff with off-label marketing information and, with a “wink and a nod,” instructed them to use it to sell Viread. CW1 and CW2 specifically recall Defendant Martin attending those same meetings in Miami and physically being at meetings during which Gilead’s sales and marketing team members were given their marching orders.

64. Importantly, at the time of the FDA presentation, according to CW1, the FDA had not approved any of Gilead’s clinical studies or theories for Viread. Thus, everything discussed at the Miami National Meeting, and not later included in the Package Labeling, was off-label.

65. Although Gilead’s clinical researchers created the FDA Briefing Document for the FDA, the entire book was intentionally provided to at least some of Gilead’s sales and marketing team at the Miami National Meeting in September 2001. DelloStritto, CW1’s supervisor and Gilead’s Regional Director for the Mid-West, instructed CW1 to make numerous copies of the FDA Briefing Document and distribute it to various members of Gilead’s Viread sales and marketing team. According to CW1, the sole purpose of Gilead instructing him or her to do so was to provide it to Gilead’s sales force so that they could market Viread with off-label information in order to increase sales.

66. Thus, even before the FDA approved Viread one month later (October 2001), Gilead representatives and employees planted the seeds of fraud by circulating off-label information to artificially boost sales of Viread.

67. Gilead and the Individual Defendants, at all relevant times (including prior and subsequent to the Class Period), knew that off-label marketing of Viread was improper. Hence, to cover its tracks, Gilead often combined its “wink and a nod” directives to its sales force
(including providing off-label materials for use by its sales force) with meaningless, perfunctory reminders that such off-label materials should not be provided to Gilead’s customers.

68. Gilead, in effect, tried to cover its tracks by directing, expecting, and encouraging off-label marketing but combining those directives with a paper trail that could be used in the event they were ever caught. Since Gilead’s scheme of illegal marketing has now been exposed, and Gilead has been caught, it will no doubt turn to its paper trail in order to attempt to avoid liability. This Court should anticipate this and not be fooled.

69. For example, one of Gilead’s common tactics was to circulate to its sales staff a cover memorandum with off-label materials attached. The body of the cover memorandum would say that the materials were for “internal use only,” but the actual off-label materials would conspicuously not contain any such limiting language. See Composite Exhibit C attached hereto (true and correct copies of internal Gilead documents demonstrating this practice). The sales and marketing staff was then directed, expected, and encouraged to remove the cover memorandum and use off-label materials to promote Viread.

70. In December 2001, Gilead hosted a weeklong national meeting for its employees at the Phoenician Hotel in Scottsdale, Arizona (the “Arizona National Meeting”). CW1 and CW2 attended this meeting, the purpose of which was to celebrate the FDA’s approval of Viread and ready the Company for an aggressive and illegal marketing campaign using off-label materials.

71. During the Arizona National Meeting, CW1 and CW2, along with numerous other members of Gilead’s sales and marketing staff, attended several Viread marketing presentations. CW1 and CW2 specifically recall Defendants Martin, Milligan, and Perry attending these meetings. During these marketing presentations, Gilead provided the sales staff with updates regarding ongoing Viread clinical trials, the results of which, until approved by the FDA, were off-label.

72. In addition, CW1 and CW2 recall attending Arizona National Meeting presentations during which they, and numerous other Gilead sales and marketing staff, received
updates concerning various clinical trials, including Study 903 and Study 907. They also participated in discussions regarding Viread’s resistance profile and potential use to combat Hepatitis B infection, even though the drug was never approved to treat Hepatitis B infection. The FDA did not include any of this information in Viread’s Package Labeling and, therefore, it was considered off-label at the time it was presented.

73. The FDA Briefing Document described Study 903 even though it was incomplete. Under the heading “Plans for Further Development,” the FDA Briefing Document states that Gilead designed Study 903 to evaluate the safety and efficacy of Viread versus Stavudine, another HIV/AIDS drug manufactured by one of Gilead’s competitors. According to the FDA Briefing Document, the forty-eight week data from Study 903 was expected to be available in early 2002. **Thus, by providing Gilead’s sales and marketing team with Study 903 information in December 2001, Gilead was providing them with off-label information on a study that was not even scheduled to reach completion until early 2002.**

74. As with Study 903, Gilead included Study 907, also off-label, in the FDA Briefing Document. Gilead designed Study 907 to evaluate the efficacy of Viread in a large population. Study 907 involved 552 patients who received varying doses of Viread and were deviating from their then-current intake levels of other HIV/AIDS drugs. Like Study 903, Gilead designed Study 907 to select patients who had experience with other HIV/AIDS drugs and had a detectable viral load. In the FDA Briefing Document, Gilead described the results of Study 907 as demonstrating that Viread had significant anti-HIV ability.

75. Gilead encouraged the sales and marketing staff to use updates on Study 907 in order to discuss the long-term safety of Viread in patients also taking other HIV/AIDS medications. According to CW1 and CW2, this off-label long-term safety data offered a clear advantage for marketing Viread because many HIV drugs are new to the marketplace and thus lack any long-term data. Accordingly, despite the off-label status of these studies, Defendants encouraged, expected, and directed Gilead’s sales and marketing staff to use this additional information to promote Viread, in violation of FDA rules and regulations.
76. CW1 and CW2 witnessed first-hand, along with Defendants Martin, Milligan, and Perry, among others, how the “wink and the nod” technique would operate to provide Gilead’s sales and marketing team with off-label information to boost Viread sales and gain an unfair advantage over competitors. For example, at meetings, such as the Arizona National Meeting, the sales and marketing staff would first attend large meetings during which Gilead executives and clinical personnel presented off-label data. Then, the sales and marketing team would break down into smaller groups for additional meetings. It was during these smaller meetings that CW1 and CW2 received specific off-label promotional material instructions. Typically, the sales and marketing team would then reconvene, where they were told to sell Viread based on what they had been told in the smaller meetings, without any specific mention of the instructions issued. In this manner, Gilead could simply present the off-label material and then quietly instruct, behind closed doors, its sales and marketing people to sell off-label, while continuing to cover itself with a paper trail at the larger meetings.

77. Both CW1 and CW2 recall that at the Arizona National Meeting, Michael Miller (“Miller”), Gilead’s Chief Virologist, made presentations to Gilead’s sales and marketing team regarding off-label Viread clinical data such as instances of HIV resistance. Among others, Defendants Martin, Milligan, and Perry were in attendance.

78. CW1 and CW2 also recall that, while at the Arizona National Meeting, Fletcher, Gilead’s Director of Marketing, instructed Gilead’s sales team to steer their Viread sales presentations toward off-label information. Among others, Defendants Martin, Perry, Milligan, and Bischofberger were present at this meeting.

79. Defendants knew that their off-label marketing violated FDA rules and regulations. In fact, the FDA concluded that, while attending the December 2001 41st Interscience Conference on Antimicrobial Agents and Chemotherapy in Chicago, Gilead made false and misleading statements about Viread at its promotional exhibit, including statements regarding the risks and efficacy associated with Viread. As explained below, on March 14, 2002, once it learned of Defendants’ misleading promotional campaign, the FDA/DDMAC issued a letter to Defendants condemning their actions (hereinafter the “Untitled FDA Letter”).
See Exhibit D attached hereto (a true and correct copy of the Untitled FDA Letter). **According to both CW1 and CW2, the statements condemned by the FDA/DDMAC letter were made by Defendant Martin. In fact, according to CW1 and CW2, it was company-wide knowledge that Martin was the cause of the Untitled FDA Letter.**

80. On January 30-31, 2002, Gilead held a regional sales and marketing meeting in Chicago (the “January 2002 Mid-West Regional Meeting”) to address slow Viread sales in the Mid-West region. CW1 recalls that during that meeting, DelloStritto, Meyers, Kristin Bennet (“Bennet”), Gilead’s Director of Training, and Mark Bernstein (“Bernstein”), one of Gilead’s Medical Science Liaisons, made it clear to Gilead’s Mid-West Therapeutic Specialists (as had been done at the Arizona National Meeting) that it was both acceptable and encouraged to violate FDA regulations and market Viread with off-label information without first obtaining a doctor’s request for such information. According to CW1, Gilead echoed that same instruction at several national meetings attended by the Individual Defendants. CW2 attended a similar meeting in Dallas, Texas (the “2002 Dallas Regional Meeting”).

81. At the January 2002 Mid-West Regional Meeting, CW1 recalls Gilead providing updates regarding Viread’s HIV resistance profile and the progression of Studies 902 and 907. Gilead designed Study 902 to test the long-term efficacy of Viread in patients with HIV who were already on other HIV/AIDS medications for at least eight weeks prior to enrollment in the study. The primary objective of Study 907, on the other hand, was to evaluate the safety and efficacy of Viread in a large population.

82. The primary object of Study 902 was to evaluate the long-term safety of three different doses of Viread and to confirm the results of previous efficacy tests. The selection criteria depended upon the amount of the HIV virus present in the patient’s body and what medication the patient was currently taking. The 189 patients in Study 902 had to already be on HIV drug therapy consisting of no more than four active medications for at least eight weeks prior to enrollment. Other requirements related to overall health including renal, hepatic, and hematologic function. Gilead included this study in the FDA Briefing document, **but any**
results that were not approved by the FDA, or any updated results from on-going patient studies, were off-label.

83. Thus, providing Gilead’s sales and marketing staff members with updated, off-label information on Study 902 would permit them to opine on the long-term safety of Viread in patients also taking other HIV/AIDS medications, despite the fact that the FDA had not approved such updated information. According to CW1 and CW2, long-term safety data for any HIV medication is invaluable for marketing such drugs because many HIV drugs are new to the marketplace, creating an inherent lack of long-term data. The ability, or in Gilead’s case, the audacity, to present such data would provide a clear advantage in the marketplace, resulting in increased sales.

84. Specifically, at the January 2002 Mid-West Regional Meeting, presenters discussed unproven and non-FDA approved theories of how Viread can allegedly remain dormant in a healthy cell, laying in wait for the HIV virus to attack the cell. CW1 recalls that Gilead used this off-label information to give Gilead’s sales and marketing team an advantage over its competition and boost Viread sales. According to CW2, presenters at the 2002 Dallas Regional Meeting discussed the same theoretical and unapproved off-label materials.

85. In addition, prior to the January 2002 Mid-West Regional Meeting, Meyers, Bennet, and DelloStritto specifically instructed CW1 to teach other Gilead Therapeutic Specialists and marketing employees how to successfully market Viread using this off-label information.

86. Specifically, CW1 was told that because he or she was skilled at manipulating potential Viread purchasers into discussing issues which required the disclosure of off-label materials, thus creating openings for discussion of off-label materials, CW1 was selected to teach other salespeople how to lead customers (i.e., physicians and other medical professionals) to these openings. CW1 did as he or she was instructed to do out of fear of losing his or her job.

87. Consequently, in addition to receiving additional off-label information from Gilead executives, CW1 trained no less than five other Therapeutic Specialists how to
successfully market Viread using off-label information. CW1 recalls that Meyers was present while CW1 instructed other Therapeutic Specialists on how to market off-label. In fact, after all was said and done, Meyers even complimented CW1’s off-label training techniques.

88. On February 11-13, 2002, Gilead held a Field Advisory Committee meeting at the New York offices of Harrison & Star, Gilead’s advertising agency (the “February 2002 Field Advisory Committee Meeting”). CW1 attended this meeting along with a select group of Viread national sales and marketing team members to discuss Viread sales and sales practices with members of Gilead’s executive departments. The attendees included CW1, five other Therapeutic Specialists, Fletcher, Gilead’s Director of Marketing until the summer of 2002, and John Windt (“Windt”), Gilead’s Associate Director of Marketing. CW1 recalls that at the meeting, Fletcher and Windt, as Gilead marketing executives, asked the Therapeutic Specialists how they were using off-label information in the field to promote and sell Viread. In response, the Therapeutic Specialists reported their experiences using off-label materials to promote Viread. As a result, CW1 is able to confirm that his or her experiences of marketing Viread with off-label information were the same as Therapeutic Specialists from all regions of the country.

89. As at other Gilead meetings, the use of off-label information in the sale and promotion of Viread was specifically discussed and encouraged at the February 2002 Field Advisory Committee Meeting, even in the presence of Gilead senior executives such as Fletcher and Windt. At the time, Fletcher was Gilead’s Director of Marketing and reported to Weisbrich, Gilead’s Vice-President of Sales and Marketing, who, in turn, reported to Inouye and Defendant Martin. Windt reported to Fletcher.

90. On February 20-22, 2002, Gilead held another regional sales and marketing meeting in Chicago (the “February 2002 Mid-West Regional Meeting”). Again, Gilead presenters told the sales and marketing staff that it was acceptable and encouraged to promote Viread using off-label information. As at previous Gilead meetings, CW1 was specifically provided with off-label information for Viread, and was encouraged to use that information, in violation of FDA rules and regulations, to make Viread sales. CW1 recalls that during the
February 2002 Mid-West Regional Meeting, Miller, Gilead’s Chief Viologist, updated the off-label Viread information. Specifically, Miller discussed Viread’s resistance profile in treatment “experienced” versus treatment “naïve” patients. At around the same time, CW2 attended a Houston regional meeting wherein Gilead presenters discussed similar substantive materials and gave the same instructions regarding the use of off-label materials.

91. According to CW1 and CW2, at the time of the February 2002 Mid-West Regional Meeting and Houston regional meeting, Gilead was testing Viread’s levels of success in patients already using HIV/AIDS medication (i.e., the experienced indication) and comparing those results to the level of success in patients who had never used HIV/AIDS medication (i.e., the naïve indication). Gilead planned to use this off-label data to expand the indication (use) of Viread into treatment of naïve patients, thus increasing sales.

92. As described above, one month later the March 14, 2002 Untitled FDA Letter advised Gilead that its representatives’ false and misleading promotional activities violated the Federal Food, Drug, and Cosmetic Act. See Exhibit D.

93. According to the Untitled FDA Letter, Gilead had falsely and misleadingly promoted Viread by stating that it contained “no toxicities,” was “extremely safe,” and was “extremely well-tolerated” despite the fact that its boxed warning and Package Labeling advised to the contrary. The FDA stated that Gilead further violated the Federal Food, Drug, and Cosmetic Act by minimizing Viread’s black boxed warning (part of the Package Labeling) and suggesting that its drug was safer than what was demonstrated by scientific evidence. In addition, the FDA stated that Gilead “engaged in false and misleading promotional activities about the efficacy of Viread,” claimed that Viread was “approved for a broad indication” and characterized Viread as a “miracle drug,” even though the FDA had not determined the clinical benefit of Viread in HIV patients.

94. The Untitled FDA Letter ordered Gilead to “immediately cease making such violative statements” and required Gilead to submit a written response to the DDMAC describing its intent and plans to comply with the DDMAC’s directives and identifying the specific date upon which Gilead planned to discontinue its illegal promotional activities.
95. On March 21, 2002, Gilead responded to the Untitled FDA Letter, assuring the DDMAC that its illegal promotional activities would cease (Gilead’s letter stated, in pertinent part, that its letter “constitute[d] Gilead’s commitment to ensure that future violative statements are not made in the promotion of Viread”). As described below, Gilead’s “commitment” did not prevent it from continuing its off label marketing scheme.

**Defendants Continue to Falsely Promote Viread During 2002, Notwithstanding their FDA Violations**

96. Nevertheless, Gilead and the Individual Defendants either specifically directed Gilead’s sales force to engage in the false, misleading, and illegal promotional and marketing activities described by CW1 and CW2 proscribed by the Untitled FDA Letter, or, at the very least, knew of the ongoing improper and illegal promotional and marketing activities but, with a “wink and a nod,” allowed them to take place, continue, and ratified them. According to CW1, Gilead made no marketing adjustments as a result of the Untitled FDA Letter. Further, both CW1 and CW2 understood (and believed it was company-wide knowledge) that it was Defendant Martin’s comments that resulted in the letter. Indeed, Gilead’s marketing misconduct continued over time, including into the Second Quarter 2003.

97. As a result of the specific activities identified, criticized, and rejected in the Untitled FDA Letter, Gilead continued planting the seeds of fraud that ultimately contributed to the artificial inflation of its sales of Viread.

98. The Untitled FDA Letter did not deter Gilead from continuing its campaign of false, improper, and illegal marketing and promotional activities, despite the fact that Gilead assured the DDMAC and the FDA that its illegal activities would cease. Instead, Gilead’s lies continued over time, including into the Second Quarter 2003.

99. On April 17-18, 2002, Gilead held a regional sales and marketing meeting in Chicago to update its Mid-West sales force with additional off-label information. CW1 attended this meeting, and specifically recalls Gilead presenters once again providing the Mid-West sales and marketing team with updated off-label Viread information and encouraging them to use the materials to illegally promote Viread.
100. On May 6, 2002, CW1 attended a meeting of Gilead’s Field Advisory Committee in New York (the “May 2002 Field Advisory Committee Meeting”). Fletcher and Inouye also attended this meeting.

101. During the May 2002 Field Advisory Committee Meeting, CW1, along with a handful of other Therapeutic Specialists from around the country, described to Gilead’s marketing officers and executives, including Inouye and Fletcher, how they were promoting Viread in all regions. Specifically, CW1 recalls discussions regarding how the sales and marketing staff was promoting Viread with off-label information. In fact, the attendees specifically discussed off-label clinical information that recently had been provided to physicians at a conference in Seattle, Washington. Again, CW1 and the other members of the Field Advisory Committee were updated with additional off-label information that Gilead would be presenting at an upcoming July 7-12, 2002, international AIDS/HIV conference in Barcelona, Spain.

102. On May 14-17, 2002, Gilead held a sales and marketing meeting in Los Angeles, California for four sales regions of the country including Chicago, Dallas, Los Angeles, and San Francisco (the “2002 Los Angeles Regional Meeting”). At the meeting, Gilead presenters provided the sales and marketing staff from these four regions with additional off-label information to use in the promotion and sale of Viread and off-label clinical and theoretical information that was going to be presented at the upcoming July 2002 international HIV/AIDS conference in Barcelona, Spain. CW1 and CW2 attended the meeting and recall that Defendants Meyers, Perry, and Martin were present when presenters directed Gilead’s sales and marketing people to use off-label information.

103. Specifically, CW1 recalls discussions at the 2002 Los Angeles Regional Meeting regarding Viread’s efficacy in the treatment of Hepatitis B infection. CW1 and the other attendees were instructed to market Viread for the treatment of HIV and Hepatitis B infection in order to boost sales, despite the fact that Viread was only approved for HIV.

104. Thus, as with all of its other meetings, at the 2002 Los Angeles Regional Meeting Gilead continued to inundate its sales and marketing staff with off-label information,
while encouraging, expecting, and directing them to use it to promote Viread in violation of FDA rules and regulations. According to CW1 and CW2, the practice of providing off-label materials to boost sales began with and ran to the highest levels of Gilead’s hierarchy, including Defendants Martin, Bischofberger, Perry, Milligan, and Lee, among others.

105. On July 15, 2002, CW1 raised concerns with DelloStritto in Chicago, Illinois regarding the use of off-label information. CW1 recalls that DelloStritto wanted more sales from the Mid-West territory and told CW1 that if CW1 used more off-label data, CW1 would get more sales.

106. Gilead’s senior management continuously and repeatedly instructed Gilead’s sales force to utilize off-label materials in order to sell greater quantities of Viread. For example, in mid-2002, Bill Strong (“Strong”), Gilead’s Region Trainer for the Dallas Region, accompanied CW2 on a number of sales calls in order to provide CW2 with “additional training” if necessary. After observing CW2’s performance, Strong attempted to train CW2 to focus in on and utilize off-label materials to more effectively market Viread. Among the off-label materials Strong emphasized were materials regarding Viread’s efficacy, safety risks, and dosages. In response, CW2 informed Strong that it was improper for CW2 to follow Strong’s directive and utilize off-label materials to market Viread.

107. On July 15, 2002, Kaiser and Robert Wallace (“Wallace”), one of Gilead’s Medical Science Liaisons, summoned CW2 to a meeting at the Atlanta airport Westin Hotel. During this meeting, Kaiser and Wallace instructed CW2 that, instead of selling Viread using the materials in the Package Labeling, he or she should sell Viread using the “theory of HIV” and the “theories behind the benefits of using Viread,” despite the fact that none of these “theories” were approved by the FDA and that many were unsupported by scientific studies. CW2 again expressed his or her reluctance to use off-label materials to market Viread.

108. In fact, as a result of his or her meeting with Kaiser and Wallace, Meyers summoned CW2 to a meeting at the Bellagio Hotel coffee shop in Las Vegas, Nevada (CW2 and Meyers were both in Las Vegas for Gilead’s September 9-13, 2002 national meeting (the “Las Vegas National Meeting”), to discuss his or her position on off-label marketing. During
this meeting, Meyers expressed his exasperation at CW2’s refusal to utilize Viread off-label marketing materials. Meyers told CW2 that if CW2 failed to fit the mold of a Gilead Therapeutic Specialist, CW2 would not be able to make his or her sales numbers. Despite CW2’s continued reluctance to use off-label materials to market Viread, CW2 assured Meyers that he or she could do his or her job and work with both Kaiser and Wallace.

109. While attending the Las Vegas National Meeting, CW1 and CW2 recall that Inouye and Defendants Milligan, Perry, Bischofberger, and Martin were also present. Once again, Gilead’s presenters provided the marketing and sales team with substantial amounts of off-label information to use to sell Viread by differentiating it from the competition. Specifically, Gilead’s presenters discussed clinical data, not yet approved by the FDA, which had been presented at the July 2002 international HIV/AIDS conference in Barcelona, Spain, as well as other new theories on Viread’s resistance profile.

110. CW1 and CW2 believe that without making improper, off-label distinctions as part of its standard sales practice, Gilead would not have had such rapid success in the promotion of Viread.

111. On October 10-11, 2002, CW1 attended another meeting of the Field Advisory Committee at Gilead’s headquarters in Foster City, California. Meyers, Kelly Seither, Gilead’s Associate Director of Marketing, and Inouye, as well as other Therapeutic Specialists from around the country attended the meeting. At the meeting, Gilead presenters provided CW1 and other Therapeutic Specialists with updated information regarding Study 903, which had just reached the three-year mark. The presenters told them how to push Viread with additional results from Study 903, results not found in the Package Labeling and not approved by the FDA.

112. On October 17, 2002, CW1 attended a regional meeting of the Mid-West Viread sales and marketing team in Chicago, Illinois. As at other national and regional meetings, Gilead presenters provided CW1 and the other members of the sales team with off-label information and encouraged them to use such information to sell Viread. Likewise, CW2 attended a regional meeting in Dallas and was given the same directives.
113. On November 1, 2002, CW1 attended a national liver disease meeting in Boston, Massachusetts. Numerous representatives from Gilead attended the meeting, including Defendants Martin and Perry, and Meyers. During the meeting, on November 2, 2002, CW1 met with Meyers to discuss the off-label marketing of Viread, and the prevalence of Gilead’s false, misleading, and improper sales practices. Rather than alleviate CW1’s concerns, Meyers instructed CW1 to use every piece of available off-label information to promote Viread, to sell Viread with the information presented at the national and regional meetings, and to do as CW1 was told.

**Defendants’ False Promotional Practices Continue in 2003, and into the Class Period**

114. On February 17, 2003, Gilead held a national meeting in Orlando, Florida. While at the meeting, CW1 and CW2 attended presentations concerning off-label information on Study 903 and Study 907 by Meredith, Gilead’s Marketing Director, and Linda Cherry (“Cherry”), Gilead’s Associate Marketing Manager. The information was presented to the sales staff in the form of key points from the off-label studies. Presenters Meredith and Cherry instructed CW1, CW2, and other members of the sales and marketing team to utilize the off-label key points to push their sales of Viread. CW1 recalls the instructions being less overt than in the past, but that when the sales teams met in smaller groups, the off-label marketing instructions were much more direct.

115. According to CW1 and CW2, Defendants Martin, Milligan, Bischofberger, Lee, and Perry, among others, were in the room when these instructions were given.

116. In May 2003, CW2 was required to attend a meeting with Packard, one of Gilead’s regional directors, at the Westin Hotel in downtown Atlanta. During this meeting, Packard criticized CW2 for his or her continued refusal to utilize off-label materials to sell Viread. Thus, throughout CW2’s career at Gilead, CW2 experienced first-hand Gilead’s constant pressure to participate in its scheme to increase Viread sales through off-label marketing tactics.
117. On June 23-27, 2003, CW2 attended a Gilead national meeting in San Francisco (the “San Francisco National Meeting”) during which Gilead continued to instruct its sales staff on how to effectively use off-label materials to market Viread. Specifically, Gilead presenters instructed Gilead’s sales staff, including CW2, on how to overcome the following four objections that potential customers raise regarding Viread: (1) “So Viread is now causing renal problems … I knew this would happen”; (2) “I am concerned about my NRTI options when my patients fail Viread”; (3) “I don’t believe in qd regimens”; and (4) “My patients tolerate Zerit and I don’t see the lipoatrophy develop in them.”

118. In order to combat these objections, during the San Francisco National Meeting, Gilead provided its sales staff, including CW2, with a memorandum which included off-label talking points to be utilized in order to convince potential customers to look past these objections and purchase Viread (the “Off-Label Talking Points”). See Exhibit E attached hereto (a true and correct copy of the Off-Label Talking Points).

119. On CW2’s information and belief, Meyers and Rich were present in the room at the San Francisco National Meeting when Gilead’s presenters provided the sales staff, including CW2, with the Off-Label Talking Points. Further, on CW2’s information and belief, Inouye and Defendants Martin, Milligan, Perry, and Lee, were present at the meeting (which was attended by all Medical Science Liaisons, Regional Directors, and National Account Managers) although they were not physically present in the room for the distribution of the Off-Label Talking Points.

120. CW2’s knowledge and belief of Defendants’ scienter is further supported by his knowledge of Gilead’s standard protocol regarding preparation for regional and national meetings.

121. According to CW2, it was standard practice for all of Gilead’s Regional Directors, prior to each national and regional meeting, to travel to Gilead’s corporate headquarters in Foster City, California to meet with Gilead’s senior management. During these meetings, which included, at various times, Defendants Martin and Perry, as well as Meyers, Weisbrich, Rich, and Helen Harris, the Regional Director of the Mid-Atlantic Region, Gilead’s
senior management would instruct Gilead’s Regional Directors on what training was to be provided to Gilead’s sales staff, including training on the use of off-label marketing materials.

122. Just like it did on a daily basis ever since Viread’s approval in October 2001, as well as in December 2001, in the Second Quarter 2003 Gilead continued to minimize important risk information (including failing to disclose potentially fatal risks) and broaden the indication for Viread. This time, Gilead’s improper and illegal campaign of lies led the FDA, through the DDMAC, to issue a warning letter.

123. On March 31-April 2, 2003, during the 15th National HIV/AIDS Update Conference in Miami, Florida, Gilead made additional off-label oral representations concerning Viread which minimized important risk information (including potentially fatal risks) and broadened the indication for Viread. As a result, on July 29, 2003, Second Quarter 2003 – the beginning of the Class Period – the FDA issued a warning letter to Gilead (the “FDA Warning Letter”). See Exhibit F attached hereto (a true and correct copy of the FDA Warning Letter).

124. According to the FDA’s website and the FDA’s Regulatory Procedures Manual, warning letters such as this are written communications from the FDA’s DDMAC, to a company notifying the company that the DDMAC considers one or more promotional pieces or practices to be illegal. If the company does not take appropriate and prompt action to correct the violation, as requested in the warning letter, there may be further enforcement actions without further notice. Warning letters are issued by the DDMAC Division Director and receive concurrence from appropriate officials in the Center for Drug Evaluation and Research.

125. The FDA Warning Letter, issued during the Class Period and addressed to defendant Martin, stated that Gilead’s illegal acts were “particularly troubling because the more than 1,500 attendees of [the 15th National HIV/AIDS Update Conference] included social workers, AIDS educators, and patients with HIV/AIDS.”

126. As stated in the FDA Warning Letter, Gilead’s lies were so outrageous that Gilead had created a new “intended use” for Viread, causing it to be misbranded.

127. According to the FDA Warning Letter, Gilead’s repeated omissions and misrepresentations regarding Viread caused “significant public health and safety concerns,”
and led the FDA to require Gilead to respond with a plan to address the “repetitive promotional activities.”

128. Defendants either specifically directed Gilead’s sales force to engage in the fraudulent, misleading, and illegal promotional and marketing activities identified in the FDA Warning Letter or, at the very least, knew of the improper and illegal promotional and marketing activities but allowed them to take place.

129. In response to Gilead’s repeated misconduct, the DDMAC requested in the FDA Warning Letter that Gilead take “action to disseminate accurate and complete information to the audience(s)” that received the misleading Viread promotional information. Thus, on November 7, 2003, Defendant Martin purported to write an open letter to all attendees of the 15th National HIV/AIDS Update Conference in Miami, Florida, entitled “IMPORTANT CORRECTION OF DRUG INFORMATION” (the “Correction Letter”). See Exhibit G attached hereto (a true and correct copy of the Correction Letter).

130. In the Correction Letter, Defendant Martin stated that the DDMAC instructed Gilead to contact conference attendees (there were over 1,500) because of misleading oral statements Gilead made in the promotion of Viread. The purpose of the Correction Letter was to provide “accurate information about Viread and [to correct] certain information as cited in the Warning Letter.”

131. More specifically and contrary to what Gilead represented at the conference, Defendant Martin described how Viread: (1) does indeed have serious, potentially fatal, side effects; (2) is a “nucleotide,” but belongs to the same class of drugs as “nucleosides”; (3) is a nucleotide, but that fact does not make it better or safer than other HIV drugs and does not make it more potent with fewer side effects (an important clinical distinction the FDA determined Gilead failed to make); (4) is approved only for use in combination with other anti-HIV medicines to treat people with HIV-1 infection; and (5) has not been proven to lower cholesterol levels.
132. As indicated by CW1 and CW2, Defendant Martin and the other Defendants knew, prior to the Correction Letter, that Gilead’s sales and marketing team was consistently instructed to market Viread with off-label information.

133. As a result of the activities identified, criticized, and rejected in the FDA Warning Letter as well as the consistent promotion of Viread by way of off-label information, Gilead caused a substantial increase in its sales of Viread during Second Quarter 2003.

134. According to CW2, the FDA Warning Letter was a result of comments made by Augustino “Tino” Quintero, one of Gilead’s Therapeutic Specialists, at the 15th National HIV/AIDS Update Conference in Miami, Florida. In accordance with Gilead’s sales force training, Quintero utilized off-label information when responding to inquiries regarding Viread. Unfortunately for Gilead, the questions Quintero was asked were posed by FDA representatives who were attending the conference to monitor sales and marketing tactics.

135. Amazingly, but not surprisingly, Gilead did not fire Quintero for making the off-label comments that he was taught to make by Gilead. Instead, subsequent to making those comments and subsequent to the issuance of the FDA Warning Letter, Gilead rewarded Quintero with membership in Gilead’s “President’s Club,” a distinction reserved for Gilead’s top sales producers.

136. CW1’s and CW2’s accounts of the numerous meetings and presentations attended by them, including national and regional meetings, provide a telling and disturbing snapshot of Gilead’s sales practices and culture. CW1 and CW2’s accounts of the significant details of Gilead’s systematic presentation of off-label information to market Viread are virtually identical. At regional meetings, Gilead encouraged CW1, CW2, and other sales team members to aggressively sell Viread with off-label information. At national meetings, Gilead instructed CW1, CW2, and other sales and marketing team members to market Viread with off-label studies and information. Indeed, CW1 and CW2’s accounts of the national meetings strongly suggest that their experiences at Gilead were neither atypical nor uncommon; rather, their experiences were the norm.
137. Gilead also provided CW1 and CW2 with numerous slides, posters, and presentation materials while attending the various meetings described above. These posters and presentations detailed the off-label clinical information presented at a given meeting. Typically, pharmaceutical manufacturers stamp all such materials with a designation that they should not be used in sales and marketing presentations – that they contain clinical research not approved by the FDA. Defendants did not do this precisely because they intended that these off-label materials would be used to market Viread.

138. According to CW1 and CW2, often the posters would be distributed with an accompanying memorandum describing them as off-label; however, the posters themselves would completely lack any off-label designation. This would enable Gilead’s sales and marketing team members to use the information in sales presentations without the customer realizing that he or she was seeing off-label information. Therefore, as it did in national and regional meetings, Gilead was able to continue its “wink and nod” tactics even with off-label posters.

B. The Effect of Defendants’ Fraudulent Promotion of Viread on Drug Wholesalers and Wholesaler Inventory Over-Stocking

139. At all relevant times, the major national wholesalers of Viread were McKesson Corp., Cardinal Health, Inc. and AmeriSource-Bergen Corp.

140. According to a former Vice President/Division Manager of national wholesaler AmeriSource-Bergen, the major national wholesalers purchase approximately ninety-percent (90%) of the drugs sold by drug manufacturers.

141. It is common knowledge among industry insiders, including Defendants, that wholesalers make very little, if any, profit when re-selling manufacturers’ drugs purchased at their usual price. In fact, according to a former Marketing Manager for national wholesaler Bergen Brunswig, wholesalers generally only realize a profit when they sell products to retailers at minimal margins, or when they stockpile mass quantities of the product prior to a price increase and then sell it at the new price. Wholesalers do this by overstocking a product at the lower price.
142. Several former Gilead employees including CW1 and CW2, a Director of National Sales, and a Regional Sales Director, confirmed that like others in the industry, Gilead executives and employees were well aware of this business strategy. In fact, according to a former Gilead Regional Sales Director, while at the San Francisco National Meeting, Defendant Perry acknowledged to several employees that wholesalers were overstocking in anticipation of a Gilead price increase. Indeed, this “buy at the old price, sell at the new price” business plan is so widely relied upon that the national wholesalers have employees whose only job is to meet with manufacturers, find out when price increases are going to take place, and assist their purchasing departments with overstocking the drugs.

143. Likewise, drug manufacturers employ trade relations people whose job is to interact with drug wholesalers and provide them with information about upcoming price increases and other product information. According to CW1, Gilead employed at least two people in this capacity.

144. As described by these industry insiders, drug manufacturers such as Gilead not only know about the “buy at the old price, sell at the new price” wholesaler strategy, but encourage and perpetuate it. They do this by informing wholesalers in advance that a price increase is going to take place. Gilead did just that, artificially boosting sales of Viread, in conjunction with its false, misleading and illegal promotion of Viread, and announced to wholesalers that a price increase for Viread would take effect in June 2003. Consequently, motivated by the temptation of increased margins and emboldened by Gilead’s illegally inflated sales, the major drug wholesalers stockpiled mass quantities of Viread in advance of the June 2003 price increase.

145. By increasing the price of Viread in June 2003, Defendants furthered their fraudulent scheme. Conveniently, the resulting wholesaler overstock confirmed the impression that Viread was in high demand and that Gilead’s financial and operational results were strong.
146. The Class Period begins on July 14, 2003. On that date, Gilead issued a press release entitled “Gilead Sciences Expects Second Quarter 2003 Financial Results Will Exceed Expectations” and reported that, because of dramatically increased demand for Viread, its financial results for the previous quarter (Second Quarter 2003) would “exceed expectations.”

In pertinent part the Company stated:

Gilead Sciences, Inc. today announced that based on initial analyses, the company expects that its financial results for the second quarter 2003 will exceed analyst expectations, driven primarily by higher product revenues.

Gilead estimates its total net revenues for the second quarter 2003 will be in the range of $236-239 million. Median total net revenues projected by analysts who report their earnings forecasts to FirstCall are $179 million. The increase in revenue was driven primarily by strong sales growth of Viread® (tenofovir disoproxil fumarate), one of the company's antiviral drugs for the treatment of HIV. Gilead expects that Viread sales will be approximately $165 million for the quarter, compared to $107 million for the first quarter of 2003. Increasing Viread sales reflect broader prescribing patterns in all commercial markets, as well as increases in U.S. wholesaler inventory levels in the second quarter in anticipation of a Viread price increase, which was implemented on June 27, 2003.

(Emphasis added.)

147. Defendants’ statements in this press release regarding Gilead’s sales of Viread, including sales results and the reasons for increased Viread sales, were materially false and misleading because, as detailed in the Section entitled “Factual Detail Undermining the Truth of Defendants’ Class Period Representations,” Defendants’ marketing and promotional activities for Viread were not in compliance with FDA approved guidelines, violated federal laws, and created serious public health and safety implications for Viread users. Defendants’ false, misleading, and illegal marketing and promotional activities prior to and during the Class Period had the cause and effect of materially increasing the volume of prescriptions for Viread at all relevant times. Their activities also had the cause and effect of materially boosting the Viread inventory of U.S. drug wholesalers. Defendants’ fraudulent Viread promotional scheme was designed to, and did, create the false and misleading public impression that demand for Viread was strong and that Viread sales would continue to increase.
148. Analysts and the market took Defendants’ July 14, 2003 press release as welcome news. Analyst Eric Schmidt of SG Cowen Securities expressed amazement at Gilead’s ability to beat expectations by such a wide margin. A July 14, 2003 Bloomberg News report quoted Schmidt as follows:

“The earnings could be as high as double the Street consensus, which would really be remarkable,” said Schmidt, who rates Gilead shares “market perform” and doesn’t own them. “I can’t remember a biotech company of this size beating expectations by two-fold before.”

149. However, some analysts cautioned that Viread sales may have been driven materially by wholesalers stocking up ahead of a June 2003 price increase, signaling weak demand for Viread. In this regard Bloomberg News reported:

It’s not clear how much of the increase in Viread sales came as wholesalers stocked up on the drug ahead of a price increase that took effect last month, said Michael King, an analyst at Banc of America Securities. “I’m going to be a little bit careful about whether the second-quarter Viread numbers represent a new level because of the inventory,” said King, who rates the stock “buy” and owns none.

150. As a result, Defendants acted quickly to neutralize analyst concerns, assuring investors that increased prescriptions (indicating increased demand) were driving Viread sales, rather than inventory overstocking.

151. Specifically, on July 14, 2003, Gilead’s spokeswoman, Amy Flood, stated in Bloomberg News: “[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking.” (Emphasis added.)

152. In response to the July 14, 2003 news, the price of Gilead shares soared by $7.97 per share in one day, closing at $67.25 on July 14, 2003 (up from the previous day’s close of $59.28 per share) – a single day increase of 13.4% and a near-record high.

153. Notwithstanding, Amy Flood’s July 14, 2003 statement was false and misleading because it was designed to, and did, create the false impression that demand for Viread was strong. In reality, as detailed herein, Defendants’ false, misleading and illegal marketing and promotion of Viread was artificially boosting sales of and demand for Viread. Moreover, since U.S. wholesaler drug inventory overstocking was driven by Defendants’
ability to raise the price for Viread in June 2003 – by showing impressive Viread prescription
increases – inventory overstocking by U.S. wholesalers played an important part in driving
Viread sales. Indeed, Defendants later admitted that inventory overstocking of Viread
negatively affected Gilead’s Third Quarter 2003 sales by virtue of significant inventory
reductions that took place as a result of the inventory buildup. See ¶162, infra.

154. Just days later, on July 29, 2003, the DDMAC issued the FDA Warning Letter.
The letter was addressed to Defendant Martin and required Gilead to cease and desist from its
repetitive, illegal promotion of Viread. The FDA was particularly concerned about Gilead’s
illegal practices because of significant public health and safety concerns, Gilead’s blatant
disregard of the FDA’s prior written warnings, and because of illegal promotional practices at
the well-attended Miami conference on March 31-April 2, 2003. See ¶¶123-127, supra. After
that conference, attended by more than 1,500 guests seeking information regarding the efficacy
of Viread, Gilead reported outstanding sales increases for Viread during Second Quarter 2003
(which included April, May and June 2003, the months following the Miami conference).

155. Indeed, on July 31, 2003, the Company issued a press release reporting its
Second Quarter 2003 results and announcing that revenues for the quarter were reportedly
$238.9 million, in line with its July 14, 2003 preannouncement:

Net revenues from product sales totaled $230.7 million, up 146 percent from the
second quarter of 2002. This growth primarily was driven by higher revenues
from Viread® (tenofovir disoproxil fumarate). Sales of Viread were $167.0
million in the second quarter of 2003, up from $44.7 million in the second quarter
of 2002 and $107.3 million in the first quarter of 2003. Viread sales growth was
primarily driven by higher prescription volume, a significant increase in U.S.
wholesaler inventories and a favorable European currency environment
compared to the same quarter last year. Gilead estimates that increased stocking
by U.S. wholesalers accounted for $25-30 million of Viread sales in the second
quarter. AmBisome® (amphotericin B) liposome for injection sales for the
second quarter of 2003 were $51.2 million, an increase of 7 percent compared to
the second quarter of 2002. Reported AmBisome sales in the second quarter of
2003 were $7.0 million higher due to the favorable currency environment
compared to the same quarter last year. On a volume basis, AmBisome sales
decreased by 4 percent in Europe compared to the second quarter 2002. Sales of
Hepsera® (adefovir dipivoxil 10 mg) totaled $12.4 million for the second quarter
of 2003, up from $5.8 million in the first quarter of 2003.

“We are very pleased to report another quarter of significant increases in product
revenues. This strong growth was fueled primarily by increasing sales of Viread
in all marketed territories and Hepsera’s uptake in the United States and
“introduction in Europe,” said John C. Martin, PhD, President and Chief Executive Officer of Gilead Sciences. “We are focused on continuing this sales momentum and increasing our market share through robust clinical data and label expansions in key territories, as well as launching Emtriva™ (emtricitabine) for HIV.”

(Emphasis added.)

156. This July 31, 2003 press release is false and misleading for the reasons set forth in ¶147 and the factual detail contained throughout this Complaint regarding Defendants false, misleading, and illegal promotion of Viread. In addition, the July 31, 2003 press release announcing “higher prescription volume,” “continuing[] sales momentum” and increased market share through “robust clinical data” was particularly egregious, given that two days before its release the FDA had issued repeated warnings and cease and desist instructions to Gilead (addressed to Defendant Martin) for its illegal Viread promotional campaign.

157. Tellingly, a mere three business days later, on August 5, 2003, Defendants began dumping their Gilead common stock at a furious pace. In total, the Individual Defendants sold 324,601 shares of Gilead at artificially inflated prices in a single month, reaping gross proceeds of $20,682,070.78. The average selling price was $64.10 per share, near the stock’s peak at $70.61 per share.


159. The Second Quarter 2003 10-Q confirmed the previously announced financial results, stating:

Net product sales were $230.7 million for the three months ended June 30, 2003, compared with $93.8 million for the quarter ended June 30, 2002, representing an increase of 146%. The increase in product sales is due to the significant increase in the volume of sales of Viread. Sales of Viread in the second quarter of 2003 were $167.0 million, or 72% of total product sales, compared to $44.7 million, or 48% of total product sales, in the second quarter of 2002. Of the $167.0 million, $115.6 million were U.S. sales and $51.4 million were international sales. International sales of Viread in the second quarter of 2003 were positively impacted by $5.0 million due to a more favorable currency environment compared to the second quarter of 2002. We believe U.S. sales in the second quarter were favorably impacted by an increase in wholesaler stocking levels in anticipation of a price increase. We estimate that this higher stocking resulted in $25.0 to $30.0 million of additional sales during the second quarter, which may adversely impact sales in the third quarter as wholesalers return to more normal inventory levels and buying patterns. We expect Viread sales to be in the range of $550 million to $600 million for the full year 2003.
In the first six months of 2003, net product sales were $386.6 million, versus $164.5 million in the comparable period of 2002, an increase of 135%. Sales of Viread for the six months ended June 30, 2003 were $274.3 million, or 71% of total product sales, compared to $71.9 million, or 44% of total product sales, in the six months ended June 30, 2002. The significant increase in Viread sales is due to increased prescription volume and an increase in U.S. wholesaler inventory levels. Of the $274.3 million in Viread sales, $184.5 million were U.S. sales and $89.8 million were international sales. International sales of Viread in the first six months of 2003 were positively impacted by $8.6 million due to the more favorable currency environment compared to the same period last year. We also recognized $92.2 million in AmBisome sales for the first six months of 2003, a 5% increase over the six months ended June 30, 2002. Reported AmBisome sales in the first six months of 2003 were $13.2 million higher due to the favorable currency environment. On a volume basis, however, AmBisome sales decreased by 7% in Europe due to increased competition.

(Emphasis added.)

160. The statements in the Second Quarter 2003 10-Q were false and misleading for the same reasons detailed in ¶¶147 and 156 herein. Defendants’ fraudulent promotion of Viread was at the core of increased Viread prescriptions. Increased Viread prescriptions contributed to Gilead’s ability to increase the price of Viread in June 2003 which, in turn, increased U.S. drug wholesalers’ motivation to overstock their Viread inventory. Defendants’ lack of candor regarding the true reasons for Viread’s success allowed Defendants to unload millions of dollars worth of Gilead stock.

161. While Defendants’ Second Quarter 2003 10-Q briefly addressed the FDA Warning Letter, it did nothing more than disclose its existence; it failed to provide anything close to full and complete disclosure of Defendants’ pervasive fraudulent marketing scheme, stating:

Regulatory Process. The products that we develop must be approved for marketing and sale and will be subject to extensive regulation by the FDA and comparable regulatory agencies in other countries. In addition, even after our products are marketed, the products and their manufacturers are subject to continual review. We are continuing clinical trials for AmBisome, Viread, Hepsera and Emtriva for currently approved and additional uses and anticipate filing for marketing approval of additional products over the next several years. If products fail to receive marketing approval on a timely basis, or if approved products are the subject of regulatory changes, actions or recalls, our results of operations may be adversely affected. For example, on August 7th, 2003, the FDA issued a written warning concerning our promotional practices of Viread. The FDA could seek to impose penalties including fines, suspensions of regulatory approvals or promotional activities for a product, product recalls, seizure of products and criminal prosecution if our promotional practices violate...
federal regulations in the future or we otherwise fail to comply with FDA regulations.

Contrary to Defendants’ Second Quarter 2003 Form 10-Q, the FDA Warning Letter was issued on July 29, 2003, not August 7, 2003. See Exhibit E. Rather, the FDA made the Warning Letter public on August 7, 2003. This distinction is important because, as demonstrated by the Individual Defendants’ trading records below, Defendants Perry and Bischofberger began unloading their shares of Gilead stock after the Warning Letter was issued, but prior to its public disclosure. Specifically, Defendants Perry and Bischofberger sold more than $3,000,000 worth of stock each between the date the FDA issued the Warning Letter and the date the FDA made the Warning Letter public. Similarly, Defendant Milligan sold almost $700,000 worth of stock on August 7, 2003, the very same day the Warning Letter became public. The very next day, on August 8, 2003, Defendant Martin sold more than $3,000,000 worth of stock.

162. On October 28, 2003, after the markets closed, Defendants issued a press release reporting Gilead’s Third Quarter 2003 financial results and revealing that Viread sales for that quarter would be materially less than expected due to the fact that the level of overstocking by wholesalers was substantially and materially more than previously reported. The press release explained that, as a result, demand for Viread in the third quarter of 2003 was met by an equal amount of sales from existing wholesaler inventory, rather than new sales, stating:

Net revenues from product sales totaled $194.1 million, up 61 percent from the third quarter of 2002. This growth primarily was driven by higher revenues from Viread® (tenofovir disoproxil fumarate). Sales of Viread were $115.4 million in the third quarter of 2003, up from $68.9 million in the third quarter of 2002, an increase of 67 percent. U.S. sales of Viread were $59.4 million, and sales outside the United States totaled $56.0 million. Viread sales growth was primarily driven by higher prescription volumes in both the United States and Europe and a favorable European currency environment compared to the same quarter last year. After reviewing NDC prescription trends, IMS inventory data and actual Viread sales, Gilead estimates there was approximately $33 to $37 million of inventory reduction by U.S. pharmaceutical wholesalers during the third quarter of 2003 following an equivalent inventory build during the second quarter of 2003. AmBisome® (amphotericin B) liposome for injection sales for the third quarter of 2003 were $51.6 million, a record high and an increase of 6 percent compared to the third quarter of 2002. Reported AmBisome sales in the third quarter of 2003 were $6.1 million higher due to the favorable currency environment compared to the same quarter last year. On a volume basis, AmBisome sales decreased by one percent in Europe compared to the third quarter of 2002. Sales of Hepsera®
(adefovir dipivoxil 10 mg) totaled $16.4 million for the third quarter of 2003, up from $12.4 million in the second quarter of 2003. Since the launch of Emtriva\textsuperscript{TM} (emtricitabine) in July 2003, sales for the third quarter of 2003 were $6.0 million.

(Emphasis added.)

163. The market reacted swiftly to this news, with the Company’s stock falling 12%, or $7.46 per share from a high of $59.46 per share on October 28, 2003, to a low of $50.27 and closing at $52.00 per share on October 29, 2003. The October 28, 2003 press release tacitly admitted that demand for Viread was not as strong as investors were previously led to believe. U.S. drug wholesalers were drawing down very material amounts of Viread inventory and Defendants’ fraudulent promotion of Viread, which artificially boosted Viread sales, was continuing to have very detrimental effects on the Company’s ability to sustain its sales, financial and operational results.

164. A reasonable investor would consider Defendants’ misrepresentations in their July 14, 2003 press release, July 14, 2003 Bloomberg News statement, July 31, 2003 press release, August 14, 2003 Form 10-Q, and October 28, 2003 press release as important in their decision making and would have viewed these misrepresented facts as significantly altering the total mix of information made available about Gilead. Had Plaintiffs, and the other members of the Class, and the marketplace known of Gilead’s true financial condition and business prospects, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Gilead securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

165. The market for Gilead’s publicly traded securities was open, well-developed, and efficient at all relevant times. As a result of Defendants’ materially false and misleading statements, Gilead’s publicly traded securities traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired Gilead publicly traded securities relying upon the integrity of the market price of Gilead’s publicly traded securities and market information relating to Gilead, and have been damaged thereby.
166. At all relevant times, the material misrepresentations particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false or misleading statements about Gilead’s sales, business, product marketing and promotion, prospects, operations and financial results. These material misstatements had the cause and effect of creating in the market an unrealistically positive assessment of Gilead and its sales, products, business, and operations and financial results, thus causing the Company’s publicly traded securities to be overvalued and artificially inflated at all relevant times. Defendants’ materially false and misleading statements during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company’s publicly traded securities at artificially inflated prices, thus causing the damages complained of herein.

**ADDITIONAL SCIENTER ALLEGATIONS**

167. As alleged herein, Defendants acted with scienter in that they knew or disregarded with deliberate recklessness that the public documents and statements, issued or disseminated in the name of the Company, were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail throughout this complaint, Defendants, by virtue of their receipt of information reflecting the true facts regarding Gilead, their control over, and/or receipt and/or modification of Gilead’s allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Gilead, participated in the fraudulent scheme alleged herein.

168. Defendants knew and/or disregarded with deliberate recklessness the falsity and misleading nature of the information that they caused to be disseminated to the investing public. The ongoing fraudulent scheme described in this complaint could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and
complicity of the personnel at the highest level of the Company, including each of the
Individual Defendants.

169. In addition to the foregoing and other facts alleged herein, the following facts
provide compelling evidence that Defendants acted with intent to deceive Gilead investors.

170. Importantly, the Individual Defendants were motivated to perpetuate the
fraudulent scheme and course of conduct described herein so that they could sell their
personally-held shares for gross proceeds of over $20 million at artificially inflated prices.

171. Within days after rebutting a Wall Street analysts’ concerns regarding inventory
overstocking (implying strong demand for Viread) and receiving their second FDA warning
letter, Defendants began to unload their Gilead shares throughout the month of August.

172. Notwithstanding their access to this and other non-public information,
Defendants disposed of the following amounts of their stock:

**John C. Martin, President and CEO:**

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<th>Number of Shares Sold</th>
<th>Price Per Share</th>
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**Mark L. Perry, Executive Vice President, Operations:**

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**John F. Milligan, Senior Vice President and CFO:**

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**Norbert W. Bischofberger, Executive Vice President, Research & Development:**

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### Anthony Caracciolo, Senior Vice President, Manufacturing:

<table>
<thead>
<tr>
<th>Date</th>
<th>Number of Shares Sold</th>
<th>Price Per Share</th>
<th>Total Value</th>
</tr>
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</table>

### William A. Lee, Senior Vice President, Research:

1. There was insufficient information in Defendant Caracciolo’s Form 4 filings with the SEC to allow Lead Plaintiffs to calculate what percentage of stock and exercised options Defendant Caracciolo sold during the Class Period. However, it is known that Defendant Caracciolo never sold any stock prior to the Class Period.
## CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

FOR VIOLATION OF FEDERAL SECURITIES LAWS: C-03-4999-MJJ

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### Date | Number of Shares Sold | Price Per Share | Total Value
---|---|---|---
08/29/2003 | 15,000 | $66.10 | $991,500

**TOTAL** | **15,000 (19.73% of stock and exercised options)** |  | **$991,500**

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173. Both the timing of the sales and the sale prices are suspicious. First, all of the Individual Defendants’ sales occurred in succession over a twenty-four day period when they were misrepresenting the Company’s Viread sales figures and ignoring the impact that would result from the FDA’s Warning Letter which sought to curtail Gilead’s false and misleading promotion of Viread. This is the first and only time that **all** of the Individual Defendants sold Gilead shares during such a short period of time.

174. Second, contrary to what Gilead disclosed in its Second Quarter 2003 Form 10-Q, the FDA Warning Letter was issued on July 29, 2003, not August 7, 2003. See Exhibit E. Rather, the FDA Warning Letter was made public on August 7, 2003. The public disclosure of the letter shines a bright light on the Individual Defendants’ suspicious sales timing. Specifically, Defendants Perry and Bischofberger sold **more than $3,000,000** worth of stock **each** between the date the FDA issued the FDA Warning Letter became public. Following suit, Defendant Martin sold more than $3,000,000 worth of stock on August 8, 2003. Third, and equally troubling, the Individual Defendants sold their shares between $61.17 to $66.10 per share, near the stock’s peak at $70.61 and prior to a low of $50.27 on October 29, 2003.

175. Additionally, the Individual Defendants’ prior trading history indicates that sales during the Class Period were both unusual and suspicious. In no time prior to the Class Period had all of the Individual Defendants ever sold stock during the same month. In fact, Defendant Caracciolo **never** sold a single share of Gilead stock prior to the Class Period. However, during a twenty-four day period in August 2003 the Individuals Defendants all sold significant amounts of stock near the height of Gilead’s artificially inflated share price for proceeds of more than $20 million.
176. The Individual Defendants’ knowledge about the false and misleading promotion of Viread, as evidenced by the Untitled FDA Letter and the FDA Warning Letter, as well as their false and misleading statements concerning sales of Viread during Second Quarter 2003, highlight the unusual nature of Defendants’ conspicuously well-timed stock sales.

177. The unusual circumstances surrounding the Individual Defendants’ sales of their stock during a 24-day period in August of 2003 further demonstrate both the Individual Defendants’ motive to commit the fraud alleged herein as well as their scienter. As described herein, Defendants acted with scienter in that they knew, or with deliberate recklessness disregarded, that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew, or with deliberate recklessness disregarded, that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Gilead, their control over, and/or receipt and/or modification of Gilead’s allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Gilead, participated in the fraudulent scheme alleged herein.

**APPLICABILITY OF PRESUMPTION OF RELIANCE:**

**FRAUD-ON-THE-MARKET DOCTRINE**

178. At all relevant times, the market for Gilead’s publicly traded securities was an efficient market for the following reasons, among others:

(a) Gilead’s securities met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) as a regulated issuer, Gilead filed periodic public reports with the SEC, including reports on Form S-3;

(c) Gilead regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases.
on the national circuits of major newswire services and through other wide-ranging public
disclosures, such as communications with the financial press and other similar reporting
services; and

(d) Gilead was followed by several securities analysts employed by major
brokerage firms who wrote reports that were distributed to the sales force and certain customers
of their respective brokerage firms. Each of these reports was publicly available and entered
the public marketplace.

179. As a result, the market for Gilead’s publicly traded securities promptly digested
current information regarding Gilead from all publicly-available sources and reflected such
information in Gilead’s securities prices. Under these circumstances, all purchasers of Gilead’s
publicly traded securities during the Class Period suffered similar injury through their purchase
of Gilead’s publicly traded securities at artificially inflated prices and a presumption of reliance
applies.

NO SAFE HARBOR

180. The federal statutory safe harbor provided for forward-looking statements under
certain circumstances does not apply to any of the allegedly false statements pleaded in this
Complaint. Many of the specific statements pleaded herein were not identified as “forward-
looking statements” when made. To the extent there were any forward-looking statements,
there were no meaningful cautionary statements identifying important factors that could cause
actual results to differ materially from those in the purportedly forward-looking statements.
Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking
statements pleaded herein, Defendants are liable for those false forward-looking statements
because at the time each of those forward-looking statements was made, the particular speaker
knew that the particular forward-looking statement was false, and/or the forward-looking
statement was authorized and/or approved by an executive officer of Gilead who knew that
those statements were false when made. Moreover, to the extent that Defendants issued any
disclosures designed to “warn” or “caution” investors of certain “risks,” those disclosures were
also false and misleading since they did not disclose that Defendants were actually engaging in
the very actions about which they purportedly warned and/or had actual knowledge of material adverse facts undermining such disclosures.

COUNT I

FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5 PROMULGATED THEREUNDER AGAINST ALL DEFENDANTS

181. Plaintiffs repeat and reallege the allegations set forth above as though fully set forth herein. This claim is asserted against all Defendants.

182. During the Class Period, Gilead and the Individual Defendants, and each of them, carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Gilead’s publicly traded securities; and (iii) cause Plaintiffs and other members of the Class to purchase Gilead’s publicly traded securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Gilead and the Individual Defendants, and each of them, took the actions set forth herein.

183. These Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Gilead's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. These Defendants are sued as primary participants in the wrongful and illegal conduct charged herein. The Individual Defendants are also sued as controlling persons of Gilead, as alleged below.

184. In addition to the duties of full disclosure imposed on Defendants as a result of their making of affirmative statements and reports, or participating in the making of affirmative statements and reports to the investing public, they each had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-X (17 C.F.R. § 210.01 et
seq.) and S-K (17 C.F.R. §229.10 et seq.) and other SEC regulations, including accurate and truthful information with respect to the Company's operations, sales, product marketing and promotion, financial condition and operational performance so that the market prices of the Company's publicly traded securities would be based on truthful, complete and accurate information.

185. Gilead and each of the Individual Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, business practices, sales performance, product marketing and promotion, operations and future prospects of Gilead as specified herein.

186. These Defendants each employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Gilead's value and performance and continued substantial sales, financial and operational growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Gilead and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Gilead's securities during the Class Period.

187. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: a) each of the Individual Defendants was a high-level executive and/or director at the Company during the Class Period; b) each of the Individual Defendants, by virtue of his responsibilities and activities as a senior executive officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal sales and marketing plans, projections and/or reports; c) each of the Individual Defendants enjoyed significant personal contact and familiarity with each other and were advised of and had access to other members of the Company's
management team, internal reports, and other data and information about the Company's financial condition and performance at all relevant times; and d) each of the Individual Defendants was aware of the Company's dissemination of information to the investing public which each knew or recklessly disregarded was materially false and misleading.

188. Each of these Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with deliberately reckless disregard for the truth in that each failed to ascertain and to disclose such facts, even though such facts were available to each of them. Such Defendants' material misrepresentations and/or omissions were done knowingly or with deliberate recklessness and for the purpose and effect of concealing Gilead's operating condition, sales, product marketing and promotional practices and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements of the Company's financial condition and performance throughout the Class Period, each of the Individual Defendants, if he did not have actual knowledge of the misrepresentations and omissions alleged, was reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

189. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market prices of Gilead’s securities were artificially inflated during the Class Period. In ignorance of the fact that market prices of Gilead’s publicly traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or disregarded with deliberate recklessness by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Gilead securities during the Class Period at artificially high prices and were damaged thereby.
190. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known of the true performance, sales, marketing, promotion and other fraudulent business practices, future prospects and intrinsic value of Gilead, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Gilead publicly traded securities during the Class Period, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

191. By virtue of the foregoing, Gilead and the Individual Defendants have each violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

192. As a direct and proximate result of Defendants’ wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

COUNT II

FOR VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS

193. Plaintiffs repeat and reiterate the allegations as set forth above as if set forth fully herein. This claim is asserted against the Individual Defendants.

194. Each of the Individual Defendants acted as a controlling person of Gilead within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions with the Company, participation in and/or awareness of the Company's operations and/or intimate knowledge of the Company's fraudulent marketing and promotions and actual performance, each of the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. Each of the Individual Defendants was provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other
statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

195. In addition, each of the Individual Defendants had direct involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

196. As set forth above, Gilead and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their controlling positions, each of the Individual Defendants is liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs, on their own behalf and on behalf of the Class, pray for relief and judgment, as follows:

A. Declaring that this action is a proper class action, and certifying Plaintiffs as class representatives pursuant to Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs’ counsel as Lead Counsel for proposed Class;

B. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants’ wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court deems appropriate.
JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

DATED: April 30, 2004

KAPLAN FOX & KILSHEIMER LLP

By: /s/

Laurence D. King (SBN 206423)

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San Francisco, CA 94111
Telephone: 415-772-4700
Fax: 415-772-4707

Liaison Counsel for Plaintiffs

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Fax: 561-750-3364

Co-Lead Counsel for Plaintiffs
PROOF OF SERVICE

I, Arthur N. Bailey, declare that I am over the age of eighteen (18) and not a party to the
within action. I am employed in the law firm of Kaplan Fox & Kilsheimer LLP, 555
Montgomery Street, San Francisco, California 94111.

On April 30, 2004, I served the attached document(s):

CONSOLIDATED AMENDED CLASS ACTION
COMPLAINT FOR VIOLATION OF FEDERAL
SECURITIES LAWS

To the below parties:

Grant P. Fondo
John C. Dwyer
COOLEY GODWARD LLP
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2155
Tel: 650-843-5458
Fax: 650-847-0663

...(BY FACSIMILE) I sent such document from facsimile machine on the above date. I
certify that said transmission was completed and that all pages were received and that a report
was generated by the facsimile machine which confirms said transmission and receipt.

...(U.S. MAIL) I placed the sealed envelope(s) for collection and mailing by following
ordinary business practices of Kaplan Fox Kilsheimer LLP. I am readily familiar with Kaplan
Fox Kilsheimer LLP’s practice for collecting and processing of correspondence for mailing
with the United States Postal Service, said practice being that, in the ordinary course of
business, correspondence with postage fully prepaid is deposited with the United States Postal
Service the same day as it is placed for collection.

XXX (PERSONAL SERVICE) I caused personal delivery of the document(s) listed above
the person(s) at the address(es) set forth below.

...(BY OVERNIGHT DELIVERY) I placed the sealed envelope(s) or package(s)
designated by the express service carrier for collection and overnight delivery by following the
ordinary business practices of Kaplan Fox Kilsheimer LLP. I am readily familiar with Kaplan
Fox Kilsheimer LLP’s practice for collecting and processing of correspondence for overnight
delivery, said practice being that, in the ordinary course of business, correspondence for
overnight delivery is deposited with delivery fees paid or provided for at the carrier’s express
service offices for next-day delivery the same day as the correspondence is placed for
collection.
I declare under penalty of perjury under the laws of the United States of America and
the State of California that the foregoing is true and correct.

Executed April 30, 2004, at San Francisco, California.

/s/

Arthur N. Bailey