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13 UNITED STATES DISTRICT COURT
14 NORTHERN DISTRICT OF CALIFORNIA
15 SAN FRANCISCO DIVISION

16 In re GILEAD SCIENCES SECURITIES
17 LITIGATION

18 _____
19 This Document Relates To:

20 ALL ACTIONS.

) Master File No. C-03-4999-MJJ
)
) CLASS ACTION
) **THIRD CONSOLIDATED AMENDED**
) **CLASS ACTION COMPLAINT FOR**
) **VIOLATION OF FEDERAL**
) **SECURITIES LAWS**
)
) DEMAND FOR JURY TRIAL
)

21
22
23 **SUMMARY AND OVERVIEW**

24 1. Lead Plaintiffs Trent St. Clare and Terry Johnson (“Plaintiffs”) bring this federal
25 securities class action individually, and on behalf of a proposed class (the “Class”) of all
26 purchasers of the publicly traded securities of Gilead (NASDAQ: GILD) between July 14, 2003
27 and October 28, 2003, inclusive (the “Class Period”), against Gilead Sciences, Inc. (“Gilead” or
28

1 the “Company”) and certain of its top officers seeking remedies under the Securities Exchange
2 Act of 1934 (the “Exchange Act”).

3 2. Gilead, based in Foster City, California, is a biopharmaceutical company that
4 discovers, develops, and commercializes pharmaceutical treatments for life-threatening
5 diseases. According to Gilead’s Forms 10-Q for the periods ending June 30, 2003 and
6 September 30, 2003, the Company has six approved commercial products, including Viread, an
7 antiretroviral agent used in combination with other drugs for the treatment of HIV infection.
8 Viread product sales are approximately 65% of Gilead’s total revenues.

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

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

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

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

8 7. In accordance with their business plan, Defendants made certain that Gilead
9 reported extremely impressive Viread sales results during the Class Period. Unfortunately for
10 investors, these results were attained through Defendants’ campaign of false and misleading
11 promotional activities for Viread found to be in violation of the Federal Food, Drug and
12 Cosmetic Act and its implementing regulations by the U.S. Food and Drug Administration
13 (“FDA”). This off-label marketing scheme materially (albeit artificially) increased Viread sales
14 and created a false demand for Viread. This skewed demand, in turn, motivated wholesalers to
15 overstock massive amounts of Viread in anticipation of an announced price increase.

16 8. To successfully implement their campaign of false and misleading promotional
17 activities, both prior to and during the Class Period, Defendants engaged in a systematic plan to
18 market Viread using clinical studies and other materials that had not received FDA approval
19 and by inducing Gilead sales and marketing representatives to make false and misleading
20 statements concerning Viread’s safety and efficacy to physicians, medical professionals and
21 others. Such tactics are generally referred to as “off-label marketing.” In doing so, Defendants
22 minimized important risk information regarding Viread, promoted Viread on the basis of
23 unproven and untested theories, and illegally “broadened the indication” for prescribing Viread
24 to patients in violation of FDA regulations by, among other things: (1) claiming it could treat
25 other infections or conditions, even though the FDA never approved such treatment; and (2)
26 promoting Viread as an “initial” or first-line treatment for HIV, even though, as discussed in
27 more detail below, the FDA did not approve Viread for such treatment until late 2003. On two
28 occasions, the FDA ordered Gilead to cease and desist this practice. Gilead blatantly ignored

1 the FDA's first warning (in a March 2002 FDA Untitled Letter) and thus received the second,
2 more dire, warning from the FDA in July 2003 (during the Class Period). Defendants' false,
3 misleading, and illegal promotional practices resulted in materially increased sales of Viread
4 during, at least, the Class Period.

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

10 10. In June 2003, Gilead announced a price increase for Viread, taking advantage of
11 the already artificially created spike in demand and enticing drug wholesalers to stock up on
12 massive amounts of Viread in anticipation of the price increase and in reliance on Gilead's
13 (artificially) inflated sales. As with Gilead's improper promotional scheme, wholesaler
14 overstocking created the appearance of increased sales. The wholesaler overstocking was made
15 possible by the creation of artificial demand for Viread through the off-label marketing scheme.

16 11. However, demand for Viread was not nearly as strong as Defendants led the
17 market to believe. In reality, the increased Viread prescriptions were driven, at all relevant
18 times, by Defendants' false and misleading Viread promotional campaign in violation of
19 federal law. In fact, as set forth more specifically below, former Gilead insiders state that
20 between 75% and 95% of Gilead's sales of Viread during the Class Period were caused by off-
21 label marketing. Given Gilead's domestic Viread sales of \$115.6 million and \$59.4 million
22 reported during the second and third quarters of 2003, respectively, when the wholesaler
23 overstocking materially increased and subsequently decreased sales, this means that between
24 \$86.7 million and \$108.92 million (second quarter 2003) and between \$44.5 million and \$56.43
25 million (third quarter 2003) of domestic Viread sales reported during the Class Period are
26 attributable to the off-label marketing scheme. Based on this fraud, Defendants released false
27 and misleading financial and operational results in order to sustain Gilead's high stock price at
28

1 the expense of Gilead's investors, the market, and, importantly, the HIV patients who depend
2 on antiretroviral drugs such as Viread to prolong their lives.

3 12. As a result, at the beginning of the Class Period, Gilead announced that overall
4 sales doubled during Second Quarter of 2003, year-over-year, largely on the strength of Viread
5 sales. The news caused Gilead's stock price to rise \$7.97 in one day, to a near-record high of
6 \$67.25.

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

11 14. Indeed, in order to sell their stock at artificially inflated prices and to sustain the
12 false and misleading impression that demand for Viread was strong, Defendants unequivocally
13 rebutted the analysts' concerns. Defendants represented that the strong Second Quarter 2003
14 Viread sales were due to "an increase in prescriptions, not inventory stocking" and that
15 "increased stocking by U.S. wholesalers accounted for \$25-\$30 million of Viread sales" (as
16 Defendants' disclosed a few months later, the amount of wholesaler overstocking was as much
17 as \$12 million larger). Defendants' unequivocal rebuttal had the intended effect of masking the
18 skewed demand for Viread and artificially maintaining Gilead's stock price long enough for
19 Defendants to dump their Gilead shares on an unsuspecting market.

20 15. In just twenty-four days (between August 5, 2003 and August 29, 2003),
21 Defendants sold in excess of 300,000 shares of Gilead stock at artificially inflated prices,
22 reaping gross proceeds in excess of \$20 million. This was the first and only time when all of
23 the Defendants sold their stock during one coordinated time period. Notably, Defendants'
24 selling spree took place just days after they had received FDA notification (sent to Gilead, care
25 of Defendant Martin on July 29, 2003, but not posted on the FDA's website until August 19,
26 2003) – for the second time since the launching of Viread – that their Viread promotional
27 campaign and off-label marketing practices violated federal law.

1 30. During the Class Period, Defendant William A. Lee (“Lee”) was the Company’s
2 Senior Vice-President, Research.

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

21 32. Throughout the Class Period, the Individual Defendants were able to, and did,
22 control the contents of the Company’s SEC filings, reports, press releases, and other public
23 statements. The Individual Defendants were provided with copies of, reviewed and approved,
24 and/or signed such filings, reports, releases, and other statements prior to or shortly after their
25 issuance and had the ability and opportunity to prevent their issuance or to cause them to be
26 corrected. The Individual Defendants also were able to, and did, directly or indirectly, control
27 the conduct of Gilead’s business, the information contained in its filings with the SEC, and its
28 public statements. Moreover, the Individual Defendants made or directed the making of

1 affirmative statements to securities analysts and the investing public at large, and participated
2 in meetings and discussions concerning such statements. Because of their positions and access
3 to material non-public information available to them but not the public, each of the Individual
4 Defendants knew that the adverse facts specified herein had not been disclosed to and were
5 being concealed from the public and that the positive representations that were being made
6 were then false and misleading. As a result, each of the Individual Defendants is responsible
7 for the accuracy of Gilead's corporate releases detailed herein as "group-published"
8 information and is therefore responsible and liable for the representations contained therein.

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

20 **CLASS ACTION ALLEGATIONS**

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

27 35. Because Gilead has millions of shares of stock outstanding, and because the
28 Company's shares were actively traded, members of the Class are so numerous that joinder of

1 all members is impracticable. As of February 27, 2004, Gilead had over 213 million shares
2 outstanding. While the exact number of Class members can only be determined by appropriate
3 discovery, Plaintiffs believe that Class members number at least in the thousands and that they
4 are geographically dispersed.

5 36. Plaintiffs' claims are typical of the claims of the members of the Class, because
6 Plaintiffs and all of the Class members sustained damages arising out of Defendants' wrongful
7 conduct complained of herein.

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

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

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

- 22 (a) whether Defendants violated the federal securities laws as alleged herein;
23 (b) whether Defendants' publicly disseminated press releases and statements
24 during the Class Period omitted and/or misrepresented material facts;
25 (c) whether Defendants breached any duty to convey material facts or to
26 correct material acts previously disseminated;
27 (d) whether Defendants participated in and pursued the fraudulent scheme or
28 course of business complained of;

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

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

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

8 **CONFIDENTIAL WITNESSES**

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

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

20 42. CW1 worked as a Gilead Therapeutic Specialist from 2001 until approximately
21 May 2003. As a Therapeutic Specialist, CW1 was responsible for promoting, marketing, and
22 selling Gilead products, namely Viread, and regularly had contact with and exposure to
23 numerous Gilead executives and Regional Directors, including the Individual Defendants (with
24 the exception of Carraciolo). CW1's territory covered the Indiana, Illinois, and Michigan
25 markets. In the course of his or her regular duties, CW1 worked with a variety of healthcare
26 professionals, including physicians, nurses, social workers, and patients. In addition, over the
27 course of CW1's employment with Gilead, CW1 attended and participated in numerous
28 national and regional Gilead meetings wherein Gilead executives specifically discussed the

1 promotion of Viread. At these meetings, as well as at other times, Gilead provided CW1 with
2 detailed information on Viread and told CW1 to use that information to aggressively promote
3 and sell Viread. Among the information provided, however, was information not approved by
4 the FDA for use in marketing and promoting Viread. Gilead executives provided this off-label
5 information despite knowing that off-label marketing violated FDA rules and regulations.
6 Further, at various times during CW1's employment with Gilead, Gilead executives
7 specifically instructed CW1 to teach and train other members of Gilead's sales and marketing
8 staff how to improperly and illegally use off-label information to market Viread.

9 43. Prior to the Class Period, CW1 was a member of Gilead's Field Marketing
10 Advisory Committee, a select committee of Gilead sales and marketing staff that periodically
11 met to discuss theories and strategies for marketing and selling Viread. Members of Gilead's
12 sales and marketing staff from various regions of the country, as well as high-ranking Gilead
13 officers and executives, including, but not limited to, Michael Inouye ("Inouye"), Gilead's
14 Senior Vice-President of Commercial Operations, James Meyers ("Meyers"), Gilead's Vice-
15 President of U.S. Sales, and various heads of marketing, such as Debbie Fletcher ("Fletcher")
16 and Sheryl Meredith ("Meredith") attended the Field Marketing Advisory Committee meetings.
17 As a result of CW1's membership on the Field Marketing Advisory Committee, and CW1's
18 other contact and communications with numerous Gilead sales people, CW1 was very familiar
19 with the sales tactics employed Company-wide and the impact of those tactics generally (and
20 off-label marketing specifically) on Viread sales.

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

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

7 46. CW2 began his or her career at Gilead in the South sales region. During that
8 time, CW2 reported to Bill Rich (“Rich”), Gilead’s Regional Director for the South. In turn,
9 Rich reported to Meyers, who reported to Inouye. Lastly, Inouye reported to the Individual
10 Defendants, including Defendant Martin, and the Board of Directors.

11 47. During CW2’s employment, CW2 also was a member of Gilead’s Dallas region
12 and Southeast regions. While a member of Gilead’s Dallas and Southeast regions, CW2
13 reported to Kirk Kaiser (“Kaiser”), a Gilead Regional Director, and later to Charles Packard
14 (“Packard”), another Gilead Regional Director. Kaiser and Packard reported to Rich. Rich, in
15 turn, reported to Meyers. Finally, Meyers reported, at various times, to either Weisbrich or
16 Fletcher (who replaced Weisbrich) and Inouye.

17 48. CW2 participated in pre-launch training for Viread, including, but not limited to,
18 Gilead seminars and Gilead home-study materials. According to CW2, during the pre-launch
19 period, Gilead was unsure whether the FDA would approve Viread and, if so, whether the
20 approved indication(s) for Viread would be broad or limited. CW2 explained that if the FDA
21 approved Viread it could be for the use of Viread over a spectrum of indications from a
22 “salvage” indication to an “experienced” indication to a “naïve” indication. A “salvage”
23 indication would limit Viread’s use to patients with long-term HIV infection. An
24 “experienced” indication would allow Viread’s use by patients previously treated with other
25 HIV drugs. Finally, a “naïve” indication would mean that Viread could be used by patients
26 recently infected with HIV but not yet exposed to a diverse treatment regimen. The “naïve”
27 indication is broader than the “experienced” indication and much broader than the “salvage”
28 indication. Gilead wanted a “naïve” indication which would allow for much higher levels of

1 Viread sales. CW2 estimates that seventy percent (70%) of AIDS drugs are sold to “naïve” and
2 “experienced” patients, while only thirty percent (30%) are sold to “salvage” patients. CW2
3 also had a large amount of contact with CW2’s peers – other Viread sales people. In fact,
4 Gilead’s sales force, including CW1 and CW2, routinely shared information regarding their
5 sales tactics, the latest information being pushed by Gilead, and their sales. As a result, CW2
6 knows that other sales people, at the insistence of Defendants, utilized off-label marketing and
7 materially increased Viread sales during the Class Period.

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

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

20 51. Nevertheless, despite his or her superiors’ pressure to market Viread utilizing
21 off-label materials, CW2 attempted to utilize off-label materials as little as possible. However,
22 as sales people in other areas of the country utilized off-label materials, the gap between sales
23 in CW2’s territory and other territories widened. Defendants then increased the already
24 substantial pressure on CW2 to use off-label marketing. CW2 did so in order to save his or her
25 job and attempt to satisfy Defendants. Ultimately, CW2 terminated his or her employment with
26 Gilead rather than follow these repeated directives to increase his or her use of off-label
27 materials.

1 information and labeling to allow physicians, pharmacists, and other medical professionals to
2 correctly use prescription drugs to treat their patients.

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

9 56. For example, it would be considered off-label for a company to market a FDA-
10 approved HIV/AIDS drug as also being effective for fighting Hepatitis B infection (which, as
11 discussed in more detail below, Gilead illegally did with Viread) if such use of the drug had not
12 been reviewed and approved by the FDA and included in the Package Labeling.¹ So long as
13 the Package Labeling lacks information regarding the HIV drug's ability to fight Hepatitis B
14 infection, the company's sales representatives are not permitted to speak about this to their
15 customers.

16 57. The only exception to this rule is if a physician or other medical professional
17 *specifically requests such information first*, via a signed written form. For example, a
18 physician may be treating a patient who has both HIV and Hepatitis B co-infection. While
19 treating the patient, the physician may notice that the patient's HIV medication appears to
20 positively impact the patient's Hepatitis B infection symptoms. In such a situation, if the
21 doctor submits a written request to the drug manufacturer, typically by utilizing a Gilead
22 inquiry form (the "Inquiry Form"), the drug manufacturer may provide the doctor with results
23 of studies which detail the drug's interaction with Hepatitis B infection, even if those results are
24 not FDA approved or found in the Package Labeling. *See* Exhibit A attached hereto (a true and
25 correct copy of a Gilead Inquiry Form).

26 _____
27 ¹ Hepatitis B is a serious disease caused by a virus that attacks the liver. The virus, which
28 is called hepatitis B virus or HBV, can cause lifelong infection, cirrhosis (scarring) of the liver,
liver cancer, liver failure, and death.

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

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

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

20 61. According to CW1, in an effort to win FDA approval for Viread, Gilead
21 submitted to the FDA a book of Viread clinical data and information, entitled the FDA
22 Advisory Committee Briefing Document (the “FDA Briefing Document”). *See* Exhibit B
23 attached hereto (a true and correct copy of the FDA Briefing Document). The FDA did not
24 include all of the information found in the FDA Briefing Document in Viread’s Package
25 Labeling. For example, the FDA Briefing Document contained information regarding Viread’s
26 impact on bone density and the incidence of bone fracture resulting from Viread use. Because
27 the FDA withheld such information from the Package Labeling, Gilead’s sales team was
28

1 prohibited from marketing Viread as being superior to other HIV drugs with regard to bone
2 density issues.

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

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

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

27 65. Importantly, at the time of the FDA presentation, according to CW1, the FDA
28 had not approved any of Gilead’s clinical studies or theories for Viread. Thus, everything

1 discussed at the Miami National Meeting, and not later included in the Package Labeling, was
2 off-label.

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

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

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

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

25 70. For example, one of Gilead's common tactics was to circulate to its sales staff a
26 cover memorandum with off-label materials attached. The body of the cover memorandum
27 would say that the materials were for "internal use only," but the actual off-label materials
28 would conspicuously not contain any such limiting language. *See* Composite Exhibit C

1 attached hereto (true and correct copies of internal Gilead documents demonstrating this
2 practice). The sales and marketing staff was then directed, expected, and encouraged to remove
3 the cover memorandum and use off-label materials to promote Viread.

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

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

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

23 74. The FDA Briefing Document described Study 903 even though it was
24 incomplete. Under the heading “Plans for Further Development,” the FDA Briefing Document
25 states that Gilead designed Study 903 to evaluate the safety and efficacy of Viread versus
26 Stavudine, another HIV/AIDS drug manufactured by one of Gilead’s competitors. According
27 to the FDA Briefing Document, the forty-eight week data from Study 903 was expected to be
28 available in early 2002. Study 903 was testing Viread as a first-line or initial antiretroviral

1 therapy regimen for treatment “naïve” patients. The success of the study was necessary for
2 Gilead to substantially increase Viread sales by expanding its indication and the patient market
3 of eligible Viread users. *Thus, by providing Gilead’s sales and marketing team with Study*
4 *903 information in December 2001, Gilead was providing them with off-label information on*
5 *a study that was not even scheduled to reach completion until early 2002. The sole purpose*
6 *of providing Study 903 to Gilead’s sales and marketing team was to arm them with data that*
7 *could be used to sell Viread off-label as a first-line therapy to treatment naïve patients and*
8 *increase sales.* As discussed in more detail below, Defendants’ scheme worked.

9 75. As with Study 903, Gilead included Study 907, also off-label, in the FDA
10 Briefing Document. Gilead designed Study 907 to evaluate the efficacy of Viread in a large
11 population. Study 907 involved 552 patients who received varying doses of Viread and were
12 deviating from their then-current intake levels of other HIV/AIDS drugs. Gilead designed
13 Study 907 to select patients who had experience with other HIV/AIDS drugs and had a
14 detectable viral load. In the FDA Briefing Document, Gilead described the results of Study
15 907 as demonstrating that Viread had significant anti-HIV activity.

16 76. Gilead encouraged the sales and marketing staff to use updates on Study 907 in
17 order to discuss the long-term safety of Viread in patients also taking other HIV/AIDS
18 medications. According to CW1 and CW2, this off-label long-term safety data offered a clear
19 advantage for marketing Viread because many HIV drugs are new to the marketplace and thus
20 lack any long-term data. Accordingly, despite the off-label status of these studies, Defendants
21 encouraged, expected, and directed Gilead’s sales and marketing staff to use this additional
22 information to promote Viread, in violation of FDA rules and regulations.

23 77. CW1 and CW2 witnessed first-hand, along with Defendants Martin, Milligan,
24 and Perry, among others, how the “wink and nod” technique would operate to provide Gilead’s
25 sales and marketing team with off-label information to boost Viread sales and gain an unfair
26 advantage over competitors. For example, at meetings, such as the Arizona National Meeting,
27 the sales and marketing staff would first attend large meetings during which Gilead executives
28 and clinical personnel presented off-label data. Then, the sales and marketing team would

1 break down into smaller groups for additional meetings. It was during these smaller meetings
2 that CW1 and CW2 received specific off-label promotional material instructions. Typically,
3 the sales and marketing team would then reconvene, where they were told to sell Viread based
4 on what they had been told in the smaller meetings, without any specific mention of the
5 instructions issued. In this manner, Gilead could simply present the off-label material and then
6 quietly instruct, behind closed doors, its sales and marketing people to sell off-label, while
7 continuing to cover itself with a paper trail at the larger meetings.

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

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

16 80. Defendants knew that their off-label marketing violated FDA rules and
17 regulations. In fact, the FDA concluded that, while attending the December 2001 41st
18 Interscience Conference on Antimicrobial Agents and Chemotherapy in Chicago, Gilead made
19 false and misleading statements about Viread at its promotional exhibit, including statements
20 regarding the risks and efficacy associated with Viread. As explained below, on March 14,
21 2002, once it learned of Defendants’ misleading promotional campaign, the FDA/DDMAC
22 issued a letter to Defendants condemning their actions (hereinafter the “Untitled FDA Letter”).
23 *See Exhibit D attached hereto (a true and correct copy of the Untitled FDA Letter). According*
24 *to both CW1 and CW2, the statements condemned by the FDA/DDMAC letter were made by*
25 *Defendant Martin. In fact, according to CW1 and CW2, it was company-wide knowledge*
26 *that Martin was the cause of the Untitled FDA Letter.*

27 81. On January 30-31, 2002, Gilead held a regional sales and marketing meeting in
28 Chicago (the “January 2002 Mid-West Regional Meeting”) to address slow Viread sales in the

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

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

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

24 84. Thus, providing Gilead’s sales and marketing staff members with updated, off-
25 label information on Study 902 would permit them to opine on the long-term safety of Viread
26 in patients also taking other HIV/AIDS medications, despite the fact that the FDA had not
27 approved such updated information. According to CW1 and CW2, long-term safety data for
28 any HIV medication is invaluable for marketing such drugs because many HIV drugs are new

1 to the marketplace, creating an inherent lack of long-term data. The ability, or in Gilead's case,
2 the audacity, to present such data would provide a clear advantage in the marketplace, resulting
3 in increased sales.

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

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

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

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

25 89. On February 11-13, 2002, Gilead held a Field Advisory Committee meeting at
26 the New York offices of Harrison & Star, Gilead's advertising agency (the "February 2002
27 Field Advisory Committee Meeting"). CW1 attended this meeting along with a select group of
28 Viread national sales and marketing team members to discuss Viread sales and sales practices

1 with members of Gilead’s executive departments. The attendees included CW1, five other
2 Therapeutic Specialists, Fletcher, Gilead’s Director of Marketing until the summer of 2002, and
3 John Windt (“Windt”), Gilead’s Associate Director of Marketing. CW1 recalls that at the
4 meeting, Fletcher and Windt, as Gilead marketing executives, asked the Therapeutic Specialists
5 how they were using off-label information in the field to promote and sell Viread. In response,
6 the Therapeutic Specialists reported their experiences using off-label materials to promote
7 Viread. As a result, CW1 is able to confirm that his or her experiences of marketing Viread
8 with off-label information were the same as Therapeutic Specialists from all regions of the
9 country. Likewise, it is reasonable to infer that other Therapeutic Specialists throughout the
10 United States materially increased their Viread sales as a result of the use of off-label
11 marketing materials. Indeed, as discussed more fully below, 85% to 95% of CW1’s Viread
12 sales were caused by off-label marketing. CW2’s sales were similarly impacted, including
13 during the Class Period. CW1 and CW2 also have stated that as a result of certain “high
14 density” HIV/AIDS population areas, such as New York City, Boston, and Washington D.C.,
15 the range of Gilead’s sales of Viread overall that were caused by off-label marketing was
16 between 75% and 95%.² It is therefore reasonable for this Court to infer that between 75% and
17 95% of all Viread sales during the Class Period were caused by the use of off-label marketing,
18 as discussed more fully below.

19 90. As at other Gilead meetings, the use of off-label information in the sale and
20 promotion of Viread was specifically discussed and encouraged at the February 2002 Field
21 Advisory Committee Meeting, even in the presence of Gilead senior executives such as
22 Fletcher and Windt. At the time, Fletcher was Gilead’s Director of Marketing and reported to
23

24 ² CW1 states that in extremely large United States HIV markets, such as New York City,
25 Boston, and Washington D.C., the percentage of sales caused by off-label marketing was likely
26 to be below 75% because physicians would be more familiar with the existence of AIDS drugs
27 and the higher incidences of HIV make it easier for sales representatives to sell larger quantities
28 of Viread (there was less of a need, and less pressure, to market off-label). As a corollary,
CW1 states that in non-HIV intensive markets, the percentage of off-label Viread sales would
fall in the 85% to 95% range because it was harder to sell vast quantities of Viread.

1 Weisbrich, Gilead's Vice-President of Sales and Marketing, who, in turn, reported to Inouye
2 and Defendant Martin. Windt reported to Fletcher.

3 91. On February 20-22, 2002, Gilead held another regional sales and marketing
4 meeting in Chicago (the "February 2002 Mid-West Regional Meeting"). Again, Gilead
5 presenters told the sales and marketing staff that it was acceptable and encouraged to promote
6 Viread using off-label information. As at previous Gilead meetings, CW1 was specifically
7 provided with off-label information for Viread, and was encouraged to use that information, in
8 violation of FDA rules and regulations, to make Viread sales. CW1 recalls that during the
9 February 2002 Mid-West Regional Meeting, Miller, Gilead's Chief Virologist, updated the off-
10 label Viread information. Specifically, Miller discussed Viread's resistance profile in treatment
11 "experienced" versus treatment "naïve" patients, as part of Gilead's ongoing, illegal efforts to
12 sell Viread to treatment naïve patients, despite the fact the FDA had not yet approved Viread
13 for such use. At around the same time, CW2 attended a Houston regional meeting wherein
14 Gilead presenters discussed similar substantive materials and gave the same instructions
15 regarding the use of off-label materials.

16 92. According to CW1 and CW2, at the time of the February 2002 Mid-West
17 Regional Meeting and Houston regional meeting, Gilead was testing Viread's levels of success
18 in patients already using HIV/AIDS medication (*i.e.*, the experienced indication) and
19 comparing those results to the level of success in patients who had never used HIV/AIDS
20 medication (*i.e.*, the naïve indication). Gilead planned to use this off-label data to expand the
21 indication (use) of Viread into treatment of naïve patients, thus increasing sales, despite the fact
22 that the FDA had approved no data at that time showing that Viread worked as a first-line
23 therapy in treatment naïve patients.

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

27 94. According to the Untitled FDA Letter, Gilead had falsely and misleadingly
28 promoted Viread by stating that it contained "no toxicities," was "extremely safe," and was

1 “extremely well-tolerated” despite the fact that its boxed warning and Package Labeling
2 advised to the contrary. The FDA stated that Gilead further violated the Federal Food, Drug,
3 and Cosmetic Act by misrepresenting Viread’s safety profile. Specifically, Gilead minimized
4 Viread’s black boxed warning (part of the Package Labeling) and suggested that its drug was
5 safer than what was demonstrated by scientific evidence. In addition, the FDA stated that
6 Gilead “engaged in false and misleading promotional activities about the efficacy of Viread,”
7 claimed that Viread was “approved for a broad indication” and characterized Viread as a
8 “miracle drug,” even though the FDA had not determined the clinical benefit of Viread in HIV
9 patients.

10 95. The Untitled FDA Letter ordered Gilead to “immediately cease making such
11 violative statements” and required Gilead to submit a written response to the DDMAC
12 describing its intent and plans to comply with the DDMAC’s directives and identifying the
13 specific date upon which Gilead planned to discontinue its illegal promotional activities.

14 96. On March 21, 2002, Gilead responded to the Untitled FDA Letter, assuring the
15 DDMAC that its illegal promotional activities would cease (Gilead’s letter stated, in pertinent
16 part, that its letter “constitute[d] Gilead’s commitment to ensure that future violative statements
17 are not made in the promotion of Viread”). As described below, Gilead’s “commitment” did
18 not prevent it from continuing its off label marketing scheme.

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

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

1 misconduct continued (and, in actuality, increased) over time, including into the Second
2 Quarter 2003.

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

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

10 100. According to CW1, in the Second Quarter of 2002, sales representatives were
11 instructed to develop relationships with gastroenterologists in order to off-label market Viread
12 for the treatment of Hepatitis B. CW1 received this instruction from his regional director. In
13 addition, the off-label use of Viread to treat Hepatitis B was discussed at sales meetings by both
14 Gilead's marketing staff and the Vice President of Sales, Meyers. CW2 confirmed that he or
15 she was instructed to and did attempt to begin to develop relationships with gastroenterologists
16 in order to induce them to prescribe Viread.

17 101. Gilead, however, *never* received FDA approval to sell or market, in any way,
18 Viread as an approved treatment for Hepatitis B (regardless of whether the patient was also
19 infected with HIV). In an effort to broaden the indication for Viread, and materially increase
20 sales, Gilead nevertheless funded a small "open-label" patient study of Viread in HIV-1 and
21 Hepatitis B virus co-infected individuals to demonstrate that Viread may work as a treatment
22 option for Hepatitis B infected patients. But, Gilead's study did not meet the FDA's
23 requirements for demonstrating the safety or efficacy of a Viread-based therapy for treating
24 Hepatitis B infection – the study only had 20 patients.

25 102. As a matter of fact, the FDA currently has a black box warning concerning the
26 use of Viread to treat Hepatitis B in HIV co-infected patients. The warning states that use of
27 Viread by co-infected patients is dangerous because there is a risk of severe acute exacerbations
28 of the Hepatitis B infection in patients when Viread is discontinued in such patients. Indeed,

1 HIV positive patients must rotate their usage of antiretroviral drugs, such as Viread, over time
2 to prevent the emergence of “HIV resistance” – a term used to describe the HIV virus’ ability
3 to mutate over time so as to render drugs, such as Viread, ineffective. Thus, according to
4 Viread’s FDA-imposed black box warning, a HIV and Hepatitis B co-infected patient who
5 stops taking Viread due to HIV resistance may, as a result, suffer even more severe, acute liver
6 damage from exacerbations of Hepatitis B. Because of these documented problems,
7 Defendants’ off-label marketing potentially and significantly endangered the very patients to
8 whom the drug was being improperly marketed.

9 103. On April 17-18, 2002, Gilead held a regional sales and marketing meeting in
10 Chicago to update its Mid-West sales force with additional off-label information. CW1
11 attended this meeting, and specifically recalls Gilead presenters once again providing the Mid-
12 West sales and marketing team with updated off-label Viread information and encouraging
13 them to use the materials to illegally promote Viread.

14 104. On May 6, 2002, CW1 attended a meeting of Gilead’s Field Advisory
15 Committee in New York (the “May 2002 Field Advisory Committee Meeting”). Fletcher and
16 Inouye also attended this meeting.

17 105. During the May 2002 Field Advisory Committee Meeting, CW1, along with a
18 handful of other Therapeutic Specialists from around the country, described to Gilead’s
19 marketing officers and executives, including Inouye and Fletcher, how they were promoting
20 Viread in all regions. Specifically, CW1 recalls discussions regarding how the sales and
21 marketing staff was promoting Viread with off-label information. In fact, the attendees
22 specifically discussed off-label clinical information that recently had been provided to
23 physicians at a conference in Seattle, Washington. Again, CW1 and the other members of the
24 Field Advisory Committee were updated with additional off-label information that Gilead
25 would be presenting at an upcoming July 7-12, 2002, international AIDS/HIV conference in
26 Barcelona, Spain. The recurring discussions between and among Therapeutic Specialists
27 during Field Marketing Advisory Committee meetings are a powerful backdrop for CW1’s
28 estimate that 75% to 95% of all Viread sales were caused by off-label marketing as well as

1 CW2's estimate that 85% to 90% of all Viread sales during the Class Period were a direct result
2 of off-label marketing.

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

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

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

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

26 110. Gilead's senior management continuously and repeatedly instructed Gilead's
27 sales force to utilize off-label materials in order to sell greater quantities of Viread. For
28 example, in mid-2002, Bill Strong ("Strong"), Gilead's Region Trainer for the Dallas Region,

1 accompanied CW2 on a number of sales calls in order to provide CW2 with “additional
2 training” if necessary. After observing CW2’s performance, Strong attempted to train CW2 to
3 increase his focus on and utilization of off-label materials to more effectively market Viread.
4 Among the off-label materials Strong emphasized were materials regarding Viread’s efficacy,
5 safety risks, and dosages. In response, CW2 informed Strong that he believed it was improper
6 for CW2 to follow Strong’s directive and utilize off-label materials to market Viread.
7 Nevertheless, CW2 was forced to utilize off-label materials in order to make sales and keep his
8 or her job.

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

16 112. In fact, as a result of his or her meeting with Kaiser and Wallace, Meyers
17 summoned CW2 to a meeting at the Bellagio Hotel coffee shop in Las Vegas, Nevada (CW2
18 and Meyers were both in Las Vegas for Gilead’s September 9-13, 2002 national meeting (the
19 “Las Vegas National Meeting”), to discuss his or her position on off-label marketing. During
20 this meeting, Meyers expressed his exasperation at CW2’s refusal to maximize his use of
21 Viread off-label marketing materials. Meyers told CW2 that if CW2 failed to fit the mold of a
22 Gilead Therapeutic Specialist, CW2 would not be able to make his or her sales numbers.
23 Despite CW2’s continued reluctance to use off-label materials to market Viread, CW2 assured
24 Meyers that he or she could do his or her job and work with both Kaiser and Wallace. In short,
25 CW2 was given no choice but to follow Defendants’ directive and utilize off-label marketing
26 materials to sell Viread. As set forth below, despite CW2’s reservations, CW2 did off-label
27 market and CW2 states that 85% to 95% of his or her sales, including those sales during the
28 Class Period, were caused by CW2’s use of off-label marketing tactics.

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

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

11 115. On October 10-11, 2002, CW1 attended another meeting of the Field Advisory
12 Committee at Gilead's headquarters in Foster City, California. Meyers, Kelly Seither, Gilead's
13 Associate Director of Marketing, and Inouye, as well as other Therapeutic Specialists from
14 around the country attended the meeting. At the meeting, Gilead presenters provided CW1 and
15 other Therapeutic Specialists with updated information regarding Study 903, which had just
16 reached the three-year mark. The presenters told them how to push Viread with additional
17 results from Study 903, results not found in the Package Labeling and not approved by the
18 FDA. The incomplete Study 903, testing Viread as a first-line therapy in treatment naïve
19 patients, was again being used by Defendants to increase Viread sales through off-label
20 marketing.

21 116. On October 17, 2002, CW1 attended a regional meeting of the Mid-West Viread
22 sales and marketing team in Chicago, Illinois. As at other national and regional meetings,
23 Gilead presenters provided CW1 and the other members of the sales team with off-label
24 information and encouraged them to use such information to sell Viread. Likewise, CW2
25 attended a regional meeting in Dallas and was given the same directives.

26 117. On November 1, 2002, CW1 attended a national liver disease meeting in
27 Boston, Massachusetts. Numerous representatives from Gilead attended the meeting, including
28 Defendants Martin and Perry, and Meyers. During the meeting, on November 2, 2002, CW1

1 met with Meyers to discuss the off-label marketing of Viread, and the prevalence of Gilead's
2 false, misleading, and improper sales practices. Rather than alleviate CW1's concerns, Meyers
3 instructed CW1 to use every piece of available off-label information to promote Viread, to sell
4 Viread with the information presented at the national and regional meetings, and to do as CW1
5 was told.

6 **Defendants' False Promotional Practices**
7 **Continue in 2003, and into the Class Period**

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

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

19 120. In May 2003, CW2 was required to attend a meeting with Packard, one of
20 Gilead's regional directors, at the Westin Hotel in downtown Atlanta. During this meeting,
21 Packard criticized CW2 for his or her continued refusal to maximize his or her utilization of
22 off-label materials to sell Viread. Thus, throughout CW2's career at Gilead, CW2 experienced
23 first-hand Gilead's constant pressure to participate in its scheme to increase Viread sales
24 through off-label marketing tactics.

25 121. On June 23-27, 2003, CW2 attended a Gilead national meeting in San Francisco
26 (the "San Francisco National Meeting") during which Gilead continued to instruct its sales staff
27 on how to effectively use off-label materials to market Viread. Specifically, Gilead presenters
28 instructed Gilead's sales staff, including CW2, on how to overcome the following four

1 objections that potential customers raise regarding Viread: (1) “So Viread is now causing renal
2 problems ... I knew this would happen”; (2) “I am concerned about my NRTI options when my
3 patients fail Viread”; (3) “I don’t believe in qd regimens”; and (4) “My patients tolerate Zerit
4 and I don’t see the lipoatrophy develop in them.”

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

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

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

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

27 126. Just like it did on a daily basis ever since Viread’s approval in October 2001, as
28 well as in December 2001, in the Second Quarter 2003 Gilead continued to minimize important

1 risk information (including failing to disclose potentially fatal risks) and broaden the indication
2 for Viread. This time, Gilead’s improper and illegal campaign of lies led the FDA, through the
3 DDMAC, to issue a warning letter.

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

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

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

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

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

27 132. Defendants either specifically directed Gilead’s sales force to engage in the
28 fraudulent, misleading, and illegal promotional and marketing activities identified in the FDA

1 Warning Letter or, at the very least, knew of the improper and illegal promotional and
2 marketing activities but allowed them to take place.

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

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

15 135. More specifically and contrary to what Gilead represented at the conference,
16 Defendant Martin described how Viread: (1) does indeed have serious, potentially fatal, side
17 effects; (2) is a "nucleotide," but belongs to the same class of drugs as "nucleosides"; (3) is a
18 nucleotide, but that fact does not make it better or safer than other HIV drugs and does not
19 make it more potent with fewer side effects (an important clinical distinction the FDA
20 determined Gilead failed to make); (4) is approved only for use in combination with other anti-
21 HIV medicines to treat people with HIV-1 infection; and (5) has not been proven to lower
22 cholesterol levels.

23 136. As indicated by CW1 and CW2, Defendant Martin and the other Defendants
24 knew, prior to the Correction Letter, that Gilead's sales and marketing team was consistently
25 instructed to market Viread with off-label information that, among other things, misrepresented
26 Viread's safety profile by minimizing critical risk information, illegally promoted Viread as a
27 first-line therapy for treatment naïve patients, and illegally promoted Viread as a treatment for
28 Hepatitis B-infected patients.

1 137. As a result of the activities identified, criticized, and rejected in the FDA
2 Warning Letter as well as the consistent promotion of Viread by way of off-label information,
3 Gilead caused a substantial increase in its sales of Viread during Second Quarter 2003. CW1
4 and CW2 state that 75% to 95% of Viread sales, including sales during the Class period, were
5 caused by off-label marketing.

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

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

17 140. CW1’s and CW2’s accounts of the numerous meetings and presentations
18 attended by them, including national and regional meetings, provide a telling and disturbing
19 snapshot of Gilead’s sales practices and culture. CW1 and CW2’s accounts of the significant
20 details of Gilead’s systematic presentation of off-label information to market Viread, and the
21 stunning impact the use of that off-label information had on Viread sales, are virtually identical.
22 At regional meetings, Gilead encouraged CW1, CW2, and other sales team members to
23 aggressively sell Viread with off-label information. At national meetings, Gilead instructed
24 CW1, CW2, and other sales and marketing team members to market Viread with off-label studies
25 and information. Indeed, CW1 and CW2’s accounts of the national meetings strongly suggest
26 that their experiences at Gilead were neither atypical nor uncommon; rather, their experiences
27 were the norm. Like CW1 and CW2, Gilead’s other sales people were required to and did
28 utilize off-label marketing materials. Indeed, both CW1 and CW2 discussed the use of off-

1 label marketing with other members of Gilead’s sales force who confirmed their use of off-
2 label information and the fact that their use of such information stimulated sales. It is,
3 therefore, reasonable to infer that 75% to 95% of Viread sales during the Class Period were
4 caused by off-label marketing as the impact is equally applicable to other Gilead salespeople as
5 it is to CW1 and CW2.

6 141. Gilead also provided CW1 and CW2 with numerous slides, posters, and
7 presentation materials while attending the various meetings described above. These posters
8 and presentations detailed the off-label clinical information presented at a given meeting.
9 Typically, pharmaceutical manufacturers stamp all such materials with a designation that they
10 should not be used in sales and marketing presentations – that they contain clinical research not
11 approved by the FDA. Defendants did not do this precisely because they intended that these
12 off-label materials would be used to market Viread.

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

20 **B. Defendants’ Off-Label Promotion Increased Sales of Viread**

21 143. At all times relevant to the Class Period, Defendants’ continued use of off-label
22 marketing of Viread worked, causing physicians to prescribe more Viread. In addition,
23 Defendants’ off-label marketing caused physicians to prescribe Viread for purposes other than
24 those approved by the FDA. Thus, off-label marketing had its intended impact – Defendants
25 significantly increased Viread sales.

26 144. According to CW1, approximately 50-60% of HIV patients were included in an
27 initial therapy group of patients who were using an HIV drug regimen for the first time.
28 Another 30-40% were part of a second therapy group of patients who were making their first

1 switch to a different HIV treatment regimen. Only approximately 20% of patients (*i.e.*, those
2 who were not part of the initial or second therapy groups) were in a rescue situation, looking
3 for a drug that would control their viral load after the virus developed a resistance to other
4 combinations of HIV drug therapies.

5 145. In other words, as a result of the manner in which Viread was approved by the
6 FDA, roughly 60% of the available HIV patient pool was unavailable to Defendants. However,
7 Viread was aggressively and illegally marketed in order to open up the maximum potential
8 patient pool. As a result, Viread was prescribed off label to these patients. Therefore,
9 according to CW1, Defendants instructed Viread sales representatives to promote studies (*i.e.*,
10 Study 903) on the effect of Viread on initial or first-line therapy patients to foster increased
11 sales. Defendants further publicized new studies on Viread and provided them to their sales
12 and marketing staff in an attempt to change physicians' views on the drug and achieve sales
13 beyond the patients authorized by the FDA.

14 146. Defendants' off-label campaign succeeded. CW1 sold approximately \$3 million
15 of Viread during his tenure at Gilead. According to CW1, approximately 85% to 95% of all of
16 CW1's Viread sales arose from off-label promotion. In fact, CW1 did not have a single sales
17 contact where off-label information was not used to market Viread. According to CW1, the
18 Company provided so much off-label data and was so forceful in instructing sales
19 representatives to utilize off-label information that off-label information was the cornerstone of
20 Gilead's Viread marketing efforts. CW1's off-label marketing took three forms: (1) marketing
21 to HIV patients co-infected with Hepatitis B; (2) marketing Viread as a first-line or initial
22 therapy for HIV infection; and (3) marketing against Viread's safety profile.

23 147. CW2's experiences mirror CW1's and CW2 corroborates CW1's analysis of the
24 material impact of off-label marketing on Gilead's sales of Viread. To be sure, CW2's Viread
25 sales were also based, in very large measure, on off-label marketing. CW2's sales analysis can
26 be divided into two parts: before and after Georgia, CW2's territory, added Viread to its
27 formulary list for the federal AIDS Drug Assistance Program ("ADAP") system.

28

1 148. According to the U.S. Department of Health and Human Services, ADAP
2 provides medications for the treatment of HIV disease. The program is funded through Title II
3 of the Ryan White CARE Act, which provides grants to States and Territories. Through
4 ADAP, grants are awarded to all 50 States. Specifically, Congress earmarks funds that must be
5 used for ADAP. The ADAP “earmark” has increased more than 1,000 percent over the past
6 five years, from \$52 million in 1996 to \$639 million in 2002. But, total ADAP spending is
7 even higher, since State ADAPs also receive money from their respective States, other CARE
8 Act programs, and through cost-savings strategies.

9 149. Approximately 128,078 people received medications through ADAP in 2000.
10 None had adequate health insurance or the financial resources necessary to cover the cost of
11 medications. On average, 73,000 clients are served each month. The ADAP in each State and
12 Territory is unique in that it decides which medications will be included in its formulary, and
13 how those medications will be distributed. Each State and Territory establishes its own
14 eligibility criteria. All require that individuals document their HIV status. Fifteen States have
15 established income eligibility at 200% or less of the Federal Poverty Level (“FPL”). Nationally,
16 more than 80% of ADAP clients have incomes at 200 percent or less of the FPL. *See*
17 <http://hab.hrsa.gov/programs/factsheets/adap1.htm>.

18 150. According to CW2, inclusion in the ADAP formulary means that all AIDS/HIV
19 patients covered by the program receive the drug and sales increase exponentially. Prior to
20 Viread’s inclusion in the Georgia ADAP formulary, CW2 sold approximately between \$10
21 million and \$15 million of Viread. Of those sales, CW2 estimates that 85%-90% were a result
22 of off-label marketing. After inclusion of the Georgia ADAP formulary (late 2002 through
23 early 2004), CW2 sold approximately between \$15 million and \$20 million of Viread. Again,
24 CW2 states that 85%-90% of those sales were caused by off-label marketing. CW2’s off-label
25 marketing involved: (1) marketing to HIV patients co-infected with Hepatitis B; (2) marketing
26 Viread as a first-line or initial therapy; and (3) marketing against Viread’s safety profile.

27 151. Based on his/her own off-label Viread sales, CW1 believes that 75%-95% of all
28 sales of Viread in the United States were the result of off-label marketing. Gilead’s domestic

1 Viread sales were \$115.6 million in the second quarter of 2003 and were \$59.4 million in the
2 third quarter of 2003. Off-label sales accounted for between \$86.7 million and \$109.82 million
3 in the second quarter of 2003 and for between \$44.5 million and \$56.43 million in the third
4 quarter of 2003. The staggering impact of off-label marketing is underscored by the
5 seriousness of the off-label marketing as described in the Untitled Letter and the FDA Warning
6 Letter.

7 152. The use of off-label marketing of Viread was so pervasive that, according to
8 CW1, sales representatives would discuss amongst themselves which off-label materials and
9 marketing tactics were generating the most sales. CW1 knows this because of CW1's
10 experiences on the Gilead Field Marketing Advisory Committee, which exposed CW1 to
11 Therapeutic Specialists and Gilead executives from all regions of the United States. In
12 addition, CW1 would discuss sales techniques with successful Therapeutic Specialists in other
13 regions of the country in an effort to find out what methods worked best for them. These
14 discussions included descriptions of off-label marketing techniques. In addition, according to a
15 former therapeutic specialist who was part of Viread's launch and with the Company through
16 June 2002, the sales force was supplied with documents listing physicians and a profile of the
17 drugs they prescribed. The list would allow sales representatives to tailor their Viread pitch to
18 suit the prescribing patterns of the various doctors and explain why Viread was superior to the
19 drugs the physician had been prescribing.

20 153. As a result of Defendants' off-market labeling, physicians prescribed Viread for
21 purposes not specifically approved by the FDA. For example, according to an AIDS-specialist
22 physician who treats between 2,000 and 2,500 AIDS patients in the Western United States, he
23 routinely uses Viread off-label to treat Hepatitis B co-infected HIV patients. In addition, this
24 physician began using Viread as a first line therapy in early 2003, before it was approved by the
25 FDA in late 2003 for this purpose, in response to unsolicited data this physician received from
26 Gilead concerning Study 903 and the use of Viread in treatment naïve patients.

27 154. As described above, Viread, during the Class Period and to this day, is not
28 indicated for treatment in patients who are co-infected with HIV and Hepatitis B – the FDA has

1 *never* approved such a use of Viread and thus prohibits any marketing of Viread for treatment
2 of co-infected patients. In fact, the FDA currently warns against this practice, as described
3 above, in a black box warning – the strongest warning possible – in the current Viread label.³

4 155. According to the “HIV Therapy Audit,” a quarterly physician survey designed to
5 monitor HIV+/AIDS patients who are seeking treatment and their associated drug and non-drug
6 therapy that was conducted by Verispan, LLC,⁴ HIV patients co-infected with Hepatitis B first
7 began using Viread in the third quarter of 2002. At that time, 55.5% of co-infected patients
8 surveyed used Viread. By the third quarter of 2003, 72.7% of co-infected patients surveyed
9 were using Viread. The use of Viread among these patients increased rapidly until 80%-100%
10 of co-infected patients were using Viread, despite the fact that: (1) no data exists that
11 conclusively demonstrates that Viread effectively treats Hepatitis B infection, with or without
12 HIV co-infection; (2) the FDA has never approved of the use of Viread in HIV and Hepatitis B
13 co-infected patients and, indeed, specifically warns against it; and (3) HIV resistance to
14 antiretrovirals, such as Viread, leads HIV positive patients to change their drug regimens,
15 exposing co-infected patients using Viread to severe acute exacerbations of Hepatitis B
16 infection.

17 156. HIV patients co-infected with Hepatitis B comprise 10% of the HIV infected
18 population, according to the United States Centers for Disease Control’s (“CDC”) Morbidity
19 and Mortality Weekly Report (“MMWR”), which is available through the CDC’s website
20

21 ³ Currently, the FDA warning label for Viread also advises healthcare professionals to
22 check HIV patients for Hepatitis B co-infection, prior to the patients taking any Viread, to
23 prevent instances of liver failure in the event an HIV patient has to change his or her drug
24 regimen and stop taking Viread due to HIV resistance.

25 ⁴ Verispan describes itself as “revolutionary health care information company” that “is
26 the leading provider of patient-centric, longitudinal data delivered in near real time as well as
27 one of the major providers of health care information overall.” “Verispan has secured rights to
28 data from more than half of all U.S. prescriptions and over 20% of all U.S. electronic medical
transactions annually. Verispan captures at least 25% of all prescriptions from 98% of all three-
digit zip codes and at least 45% of all prescriptions from almost 80% of all zip codes. This
pervasive data coverage means that Verispan can provide better insight into prescription and
medical activity at the national, regional and individual prescriber level than ever before
possible.” See <http://www.verispan.com/about/>.

1 (<http://www.cdc.gov/mmwr>). Likewise, an informal survey of AIDS physicians resulted in
2 reported co-infection rates of between 5% and 30%. As a result of improperly marketing
3 Viread to co-infected patients, for whom Viread was not indicated, Defendants materially
4 increased Viread sales.

5 157. According to the CDC MMWR, there are approximately 660,000 HIV patients
6 in the United States who are aware of their diagnosis. Of these 660,000 patients, in 2002,
7 approximately 350,000 were on an antiretroviral therapy such as Viread. *See Reuters*
8 *NewsMedia, Viread Effective in Untreated HIV Patients* (Feb. 25, 2002). According to Gilead,
9 approximately 360,000 HIV patients actively receive antiretroviral treatment. *See*
10 http://www.gilead.com/wt/ltd_slideshow/hiv. Based on a conservative co-infection rate of 10%
11 and the Verispan data showing that 71.4% and 72.7% of surveyed co-infected patients were on
12 Viread in the second and third quarters of 2003, respectively, that means that approximately
13 25,000 HIV and Hepatitis B co-infected patients were taking Viread during each of the second
14 quarter of 2003 and the third quarter of 2003.

15 158. According to the Physician's Desk Reference, Viread has a once a day dosing
16 regimen and is normally distributed in sealed bottles of 30 tablets. A one month supply of
17 Viread costs approximately \$460 to \$480. Gilead's off-label marketing of Viread, which
18 resulted in 25,000 co-infected patients taking Viread, therefore resulted in an additional \$11.5
19 million per month in revenue during the second and third quarters of 2003.

20 159. Defendants also increased Viread sales by improperly marketing Viread as a
21 first-line (initial) therapy for treatment naïve HIV patients, before Viread was indicated for
22 these patients. Not content to await FDA approval of Viread as a first-line antiretroviral drug,
23 Defendants immediately used off-label marketing to sell Viread as a first-line HIV therapy
24 upon launching Viread in October 2001.

25 160. According to an Infectious Disease Specialist in the Southeast United States
26 with a large AIDS practice that comprises 40% to 45% of his total practice, he began to receive
27 unsolicited advice on using Viread as a first line HIV therapy from Gilead sales representatives
28 shortly after Viread was launched in October 2001. He then began to use Viread as a first line

1 therapy in 2002. A second Infectious Disease Specialist in the Southeast United States also
2 received unsolicited material from Gilead representatives on the use of Viread as first line
3 therapy upon Viread's October 2001 launch. The second Infectious Disease Specialist began
4 using Viread as a first line therapy in 2001.

5 161. According to the HIV Therapy Audit, in the fourth quarter of 2001 (shortly after
6 its launch), Viread had an 11.2% market share as a first-line antiretroviral drug. By the fourth
7 quarter of 2003, Defendants' improper off-label marketing had increased this market share to
8 27.4%. During the Class Period, the third quarter of 2003, Gilead's Viread market share for
9 treatment naïve patients was 23.8%.

10 162. Until mid-October 2003, Viread was not indicated for use in treatment naïve
11 patients. According to the HIV Therapy Audit, during the second and third quarters of 2003,
12 there were 81,210 and 83,440 HIV positive patients on Viread, respectively. Approximately
13 23.8% of these patients surveyed were improperly receiving Viread as a first-line therapy.
14 Defendants' off label marketing of Viread for treatment naïve patients increased sales of Viread
15 by more than 20%. Thus, in the second quarter of 2003, Gilead's 23.8% first-line treatment
16 market share translated to approximately 19,290 patients surveyed who were on Viread. In the
17 third quarter of 2003, Gilead's 23.8% first-line treatment market share translated to
18 approximately 19,840 patients surveyed who were on Viread. Applying this 23.8% to Gilead's
19 entire second quarter 2003 domestic sales of Viread of \$115.6 million, Defendants made
20 approximately \$27.51 million on this type of off-label marketing during the second quarter of
21 2003. Extrapolating this 23.8% over Gilead's entire reported third quarter 2003 domestic sales
22 of Viread of \$59.4 million, Defendants made \$14.14 million on this type of off-label marketing
23 in the third quarter of 2003.

24 163. Gilead also marketed Viread against its safety label. Gilead sales
25 representatives routinely represented that Viread had no side effects and was as safe as placebo.
26 According to the Medical Director of a large AIDS clinic in Washington, D.C. who uses Viread
27 routinely in patients, Gilead representatives told him that Viread was completely safe – as safe
28 as placebo. In particular, the Medical Director said that the Gilead representatives marketed

1 Viread as completely safe with regard to renal function. The Medical Director stated that *based*
2 *on these false representations (off-label marketing)*, he wrote prescriptions for Viread. Since
3 prescribing Viread based on false safety marketing, the Medical Director has had patients
4 develop renal (kidney) failure due to Viread and is now cautious about using Viread. This
5 Medical Director stated that he felt he had been deceived about Viread's safety profile by
6 Gilead drug sales representatives.

7 164. Similarly, an AIDS specialist from the Western United States was told by Gilead
8 representatives that Viread was a safe drug without nephrotoxicity (risk of renal problems).
9 This AIDS specialist has since found that nephrotoxicity is a problem with Viread – contrary to
10 what Gilead sales representatives told her. Likewise, a Doctor of Pharmacy practicing in the
11 Mid-West United States, who has 20% of the patients in her AIDS clinic on Viread, was told
12 by Gilead sales representatives that Viread had a safety profile similar to placebo. Since then,
13 she has seen increasing frequency of renal insufficiency in patients on Viread – in direct
14 contravention to Gilead's off-label marketing tactics.

15 165. Based upon the Versipan data, data collected from public sources, and the
16 estimates of confidential sources, including many physicians, approximately 83% of all Viread
17 prescriptions were the result of Defendants' off-label marketing scheme. In the second and
18 third quarters of 2003, Gilead had a 23.8% market share for first-line therapy in HIV patients, a
19 26% market share for co-infected patients, and an estimated 33.3% market share for marketing
20 against the safety label. This data, which includes the Verispan data, is therefore in line with
21 and corroborates CW1 and CW2's estimates that 75% to 95% of Viread sales during the Class
22 Period were caused by off-label marketing.

23 166. The Verispan data is based on surveys of physicians. As a result, it is not a
24 complete picture of Viread's use as a result of off-label marketing. Gilead's financial
25 statements in their SEC filings, however, corroborate the Verispan data. Gilead's financial data
26 shows Viread sales growing from its launch through the Class Period from revenue of \$13
27 million to revenue of \$115 million. At the same time, Viread sales became a larger percentage
28 of Gilead's total sales from 22.1% at the fourth quarter of 2001 to 59.5% at the third quarter of

1 2003. The increase in Viread sales corresponds with the Verispan data showing an increase in
2 market share of for Viread, due in part to increased sales as first line therapy and to co-infected
3 patients, and sales resulting from marketing against Viread's safety profile.

4 167. In the second quarter of 2003, Gilead reported total domestic Viread sales of
5 \$115.6 million. In the third quarter of 2003, Gilead reported total domestic Viread sales of
6 \$59.4 million. Based on the Verispan data, because approximately 83% of Viread sales were
7 the result of improper off-label marketing, then Gilead's second quarter 2003 domestic Viread
8 sales of \$115.6 million were overstated by approximately \$95.95 million. Similarly, Gilead's
9 third quarter 2003 domestic Viread sales of \$59.4 million were overstated by approximately
10 \$49.3 million. Without Gilead's illegal and improper off-label marketing tactics, Gilead only
11 would have had domestic Viread sales of \$19.65 million in the second quarter of 2003 and
12 \$10.1 million in the third quarter of 2003. In the second quarter of 2003, Gilead reported total
13 consolidated sales of \$230,700,000. Without Gilead's illegal and improper off-label marketing
14 tactics, which materially boosted domestic Viread sales, Gilead only would have had total
15 consolidated sales of \$134,750,000. Therefore, Gilead's total consolidated sales for the second
16 quarter of 2003 were overstated by approximately 42%. In the third quarter of 2003, Gilead
17 reported total consolidated sales of \$194,075,000. Without Gilead's illegal and improper off-
18 label marketing tactics, which materially boosted domestic Viread sales, Gilead only would
19 have had total consolidated sales of \$144,775,000. Therefore, Gilead's total consolidated sales
20 for the third quarter of 2003 were overstated by approximately 25%.

21 168. Based on the estimations of CW1 and CW2, because between 75% and 95% of
22 Viread sales were the result of improper off-label marketing, then Gilead's second quarter 2003
23 domestic Viread sales of \$115.6 million were overstated by between \$86.7 million and \$109.82
24 million and Gilead's third quarter 2003 domestic Viread sales of \$59.4 million were overstated
25 by between \$44.5 million and \$56.43 million. Without Gilead's illegal and improper off-label
26 marketing tactics, according to CW1 and CW2, Gilead only would have had domestic Viread
27 sales between \$28.9 million and \$5.78 million and between \$14.9 million and \$2.97 million in
28 the second and third quarters of 2003, respectively. In the second quarter, Gilead reported total

1 consolidated sales of \$230,700,000. Without Gilead's illegal and improper off-label marketing
2 tactics, which materially boosted domestic Viread sales, Gilead only would have had total
3 consolidated sales between \$144,000,000 and \$120,880,000. Therefore, Gilead's total
4 consolidated sales for the second quarter of 2003 were overstated by between approximately
5 38% and 48%. In the third quarter, Gilead reported total consolidated sales of \$194,075,000.
6 Without Gilead's illegal and improper off-label marketing tactics, which materially boosted
7 domestic Viread sales, Gilead only would have had total consolidated sales between
8 \$149,575,000 and \$137,645,000. Therefore, Gilead's total consolidated sales for the third
9 quarter of 2003 were overstated by between approximately 23% and 29%.

10 169. Whether using the 83% estimate of Viread sales resulting from off-label
11 marketing extrapolated from the Verispan data or whether using the 75% to 95% estimate of
12 Viread sales resulting from off-label marketing as calculated by CW1 and CW2, the results are
13 not only material, but stunning.

14 **C. The Effect of Defendants' Fraudulent Promotion of Viread on**
15 **Drug Wholesalers and Wholesaler Inventory Over-Stocking**

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

18 171. According to a former Vice President/Division Manager of national wholesaler
19 AmeriSource-Bergen, the major national wholesalers purchase approximately ninety-percent
20 (90%) of the drugs sold by drug manufacturers.

21 172. It is common knowledge among industry insiders, including Defendants, that
22 wholesalers make very little, if any, profit when re-selling manufacturers' drugs purchased at
23 their usual price. In fact, according to a former Marketing Manager for national wholesaler
24 Bergen Brunswig, wholesalers generally only realize a profit when they sell products to
25 retailers at minimal margins, or when they stockpile mass quantities of the product prior to a
26 price increase and then sell it at the new price. Wholesalers do this by overstocking a product
27 at the lower price.

1 173. Several former Gilead employees including CW1 and CW2, a Director of
2 National Sales, and a Regional Sales Director, confirmed that like others in the industry, Gilead
3 executives and employees were well aware of this business strategy. In fact, according to a
4 former Gilead Regional Sales Director, while at the San Francisco National Meeting,
5 Defendant Perry acknowledged to several employees that wholesalers were overstocking in
6 anticipation of a Gilead price increase. Indeed, this “buy at the old price, sell at the new price”
7 business plan is so widely relied upon that the national wholesalers have employees whose only
8 job is to meet with manufacturers, find out when price increases are going to take place, and
9 assist their purchasing departments with overstocking the drugs.

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

14 175. As described by these industry insiders, drug manufacturers such as Gilead not
15 only know about the “buy at the old price, sell at the new price” wholesaler strategy, but
16 encourage and perpetuate it. They do this by informing wholesalers in advance that a price
17 increase is going to take place. Gilead did just that, artificially boosting sales of Viread, in
18 conjunction with its false, misleading and illegal promotion of Viread, and announced to
19 wholesalers that a price increase for Viread would take effect in June 2003. Consequently,
20 motivated by the temptation of increased margins and emboldened by Gilead’s illegally inflated
21 sales and artificially inflated demand for Viread, the major drug wholesalers stockpiled mass
22 quantities of Viread in advance of the June 2003 price increase. This wholesaler stockpiling
23 would not have occurred but for the off-label marketing and the resulting creation of an
24 artificially increased demand for Viread.

25 176. By increasing the price of Viread in June 2003, Defendants furthered their
26 fraudulent scheme. Conveniently, the resulting wholesaler overstock confirmed the impression
27 that Viread was in high demand and that Gilead’s financial and operational results were strong.
28

1 177. Defendants routinely used wholesaler sales to improve overall Viread sales. For
2 example, on April 2, 2003, Meyers sent an e-mail to sales representatives, including Rich,
3 DelloStritto, and Kaiser, among others, discussing the need to meet sales figures for Viread.
4 The e-mail was copied to, among others, defendants Martin, Perry, Milligan, and
5 Bischofberger. Attached to the e-mail was a chart entitled “Kicker Bonus Forecast.” The
6 Kicker Bonus Forecast set forth Viread’s Financial Forecast of sales from October 2002
7 through April 2003 and the corresponding actual sales. The chart indicated that to meet the
8 seven month sales forecast, April’s actual Viread sales needed to be \$38.3 million, \$7 million
9 more than the April forecast of \$31.9 million. According to CW1, Gilead made the sales
10 numbers by overloading wholesalers with product. Wholesalers were willing to overstock
11 because they were tricked into believing that the off-label marketing-created “demand” for
12 Viread was real.

13 **DEFENDANTS’ CLASS PERIOD MATERIALLY**
14 **FALSE AND MISLEADING STATEMENTS**

15 178. The Class Period begins on July 14, 2003. On that date, Gilead issued a press
16 release entitled “Gilead Sciences Expects Second Quarter 2003 Financial Results Will Exceed
17 Expectations” and reported that, because of dramatically increased demand for Viread, its
18 financial results for the previous quarter (Second Quarter 2003) would “exceed expectations.”
19 In pertinent part the Company stated:

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

23 Gilead estimates its total net revenues for the second quarter 2003 will be in the
24 range of \$236-239 million. Median total net revenues projected by analysts who
25 report their earnings forecasts to FirstCall are \$179 million. ***The increase in
26 revenue was driven primarily by strong sales growth of Viread® (tenofovir
27 disoproxil fumarate), one of the company's antiviral drugs for the treatment of
28 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.)

1 179. Defendants' statements in this press release regarding Gilead's sales of Viread,
2 including sales results and the reasons for increased Viread sales, were materially false and
3 misleading because, as detailed in the Section entitled "Factual Detail Undermining the Truth
4 of Defendants' Class Period Representations," Defendants' marketing and promotional
5 activities for Viread were not in compliance with FDA approved guidelines, violated federal
6 laws, and created serious public health and safety implications for Viread users. Defendants'
7 false, misleading, and illegal marketing and promotional activities prior to and during the Class
8 Period had the cause and effect of materially increasing the volume of prescriptions for Viread
9 at all relevant times. Their activities also had the cause and effect of materially boosting the
10 Viread inventory of U.S. drug wholesalers. Defendants' fraudulent Viread promotional scheme
11 was designed to, and did, create the false and misleading public impression that demand for
12 Viread was strong and that Viread sales would continue to increase.

13 180. Analysts and the market took Defendants' July 14, 2003 press release as
14 welcome news. Analyst Eric Schmidt of SG Cowen Securities expressed amazement at
15 Gilead's ability to beat expectations by such a wide margin. A July 14, 2003 *Bloomberg News*
16 report quoted Schmidt as follows:

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

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

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

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

4 183. Specifically, on July 14, 2003, Gilead's spokeswoman, Amy Flood, stated in
5 *Bloomberg News*: "[t]he main reason for the jump in Viread sales is an increase in
6 prescriptions, **not inventory stocking.**" (Emphasis added.)

7 184. In response to the July 14, 2003 news, the price of Gilead shares soared by \$7.97
8 per share in one day, closing at \$67.25 on July 14, 2003 (up from the previous day's close of
9 \$59.28 per share) – a single day increase of 13.4% and a near-record high.

10 185. Notwithstanding, Amy Flood's July 14, 2003 statement was false and
11 misleading because it was designed to, and did, create the false impression that demand for
12 Viread was strong. In reality, as detailed herein, Defendants' false, misleading and illegal
13 marketing and promotion of Viread was artificially boosting sales of and demand for Viread.
14 Moreover, since U.S. wholesaler drug inventory overstocking was driven by Defendants'
15 ability to raise the price for Viread in June 2003 – by showing impressive Viread prescription
16 increases – inventory overstocking by U.S. wholesalers played an important part in driving
17 Viread sales. Indeed, Defendants later admitted that inventory overstocking of Viread
18 negatively affected Gilead's Third Quarter 2003 sales by virtue of significant inventory
19 reductions that took place as a result of the inventory buildup. *See* ¶194, *infra*.

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

1 187. Indeed, on July 31, 2003, the Company issued a press release reporting its
2 Second Quarter 2003 results and announcing that revenues for the quarter were reportedly
3 \$238.9 million, in line with its July 14, 2003 preannouncement:

4 Net revenues from product sales totaled \$230.7 million, **up 146 percent from the**
5 **second quarter of 2002.** This growth primarily was driven by higher revenues
6 from Viread® (tenofovir disoproxil fumarate). Sales of Viread were \$167.0
7 million in the second quarter of 2003, up from \$44.7 million in the second quarter
8 of 2002 and \$107.3 million in the first quarter of 2003. **Viread sales growth was**
9 **primarily driven by higher prescription volume, a significant increase in U.S.**
10 **wholesaler inventories and a favorable European currency environment**
11 **compared to the same quarter last year. Gilead estimates that increased stocking**
12 **by U.S. wholesalers accounted for \$25-30 million of Viread sales in the second**
13 **quarter.** AmBisome® (amphotericin B) liposome for injection sales for the
14 second quarter of 2003 were \$51.2 million, an increase of 7 percent compared to
15 the second quarter of 2002. Reported AmBisome sales in the second quarter of
16 2003 were \$7.0 million higher due to the favorable currency environment
17 compared to the same quarter last year. On a volume basis, AmBisome sales
18 decreased by 4 percent in Europe compared to the second quarter 2002. Sales of
19 Hepsera® (adefovir dipivoxil 10 mg) totaled \$12.4 million for the second quarter
20 of 2003, up from \$5.8 million in the first quarter of 2003.

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

(Emphasis added.)

187. This July 31, 2003 press release is false and misleading for the reasons set forth
in ¶179 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 and label expansions” 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.

189. 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

1 Defendants sold 324,601 shares of Gilead at artificially inflated prices in a single month,
2 reaping gross proceeds of \$20,682,070.78. The average selling price was \$64.10 per share,
3 near the stock's peak at \$70.61 per share.

4 190. On August 14, 2003, Gilead filed its quarterly report on Form 10-Q, for Second
5 Quarter 2003, ended June 30, 2003. The 10-Q was signed by Defendants Martin and Milligan.

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

8 *Net product sales* were \$230.7 million for the three months ended June 30, 2003,
9 compared with \$93.8 million for the quarter ended June 30, 2002, representing an
10 *increase of 146%. The increase in product sales is due to the significant*
11 *increase in the volume of sales of Viread.* Sales of Viread in the second quarter
12 of 2003 were \$167.0 million, or 72% of total product sales, compared to \$44.7
13 million, or 48% of total product sales, in the second quarter of 2002. Of the
14 \$167.0 million, \$115.6 million were U.S. sales and \$51.4 million were
15 international sales. International sales of Viread in the second quarter of 2003
16 were positively impacted by \$5.0 million due to a more favorable currency
17 environment compared to the second quarter of 2002. *We believe U.S. sales in the*
18 *second quarter were favorably impacted by an increase in wholesaler stocking*
19 *levels in anticipation of a price increase. We estimate that this higher stocking*
20 *resulted in \$25.0 to \$30.0 million of additional sales during the second quarter,*
21 *which may adversely impact sales in the third quarter as wholesalers return to*
22 *more normal inventory levels and buying patterns. We expect Viread sales to be*
23 *in the range of \$550 million to \$600 million for the full year 2003.*

16 * * *

17 In the first six months of 2003, net product sales were \$386.6 million, versus
18 \$164.5 million in the comparable period of 2002, an increase of 135%. Sales of
19 Viread for the six months ended June 30, 2003 were \$274.3 million, or 71% of
20 total product sales, compared to \$71.9 million, or 44% of total product sales, in
21 the six months ended June 30, 2002. *The significant increase in Viread sales is*
22 *due to increased prescription volume and an increase in U.S. wholesaler*
23 *inventory levels.* Of the \$274.3 million in Viread sales, \$184.5 million were U.S.
24 sales and \$89.8 million were international sales. International sales of Viread in
25 the first six months of 2003 were positively impacted by \$8.6 million due to the
26 more favorable currency environment compared to the same period last year. We
27 also recognized \$92.2 million in AmBisome sales for the first six months of 2003,
28 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.

25 (Emphasis added.)

26 192. The statements in the Second Quarter 2003 10-Q were false and misleading for
27 the same reasons detailed in ¶¶179 and 188 herein. Defendants' fraudulent promotion of
28 Viread was at the core of increased Viread prescriptions. Increased Viread prescriptions

1 contributed to Gilead's ability to increase the price of Viread in June 2003 which, in turn,
2 increased U.S. drug wholesalers' motivation to overstock their Viread inventory. Defendants'
3 lack of candor regarding the true reasons for Viread's success allowed Defendants to unload
4 millions of dollars worth of Gilead stock.

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

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

25 Contrary to Defendants' Second Quarter 2003 Form 10-Q, *the FDA Warning Letter was*
26 *issued on July 29, 2003, not August 7, 2003.* See Exhibit E. Rather, the FDA made the
27 Warning Letter public on August 7, 2003. This distinction is important because, as
28 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.

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

7 Net revenues from product sales totaled \$194.1 million, up 61 percent from the
8 third quarter of 2002. This growth primarily was driven by higher revenues from
9 Viread® (tenofovir disoproxil fumarate). Sales of Viread were \$115.4 million in
10 the third quarter of 2003, up from \$68.9 million in the third quarter of 2002, an
11 increase of 67 percent. U.S. sales of Viread were \$59.4 million, and sales outside
12 the United States totaled \$56.0 million. Viread sales growth was primarily driven
13 by higher prescription volumes in both the United States and Europe and a
14 favorable European currency environment compared to the same quarter last year.
15 After reviewing NDC prescription trends, IMS inventory data and actual Viread
16 sales, ***Gilead estimates there was approximately \$33 to \$37 million of inventory
17 reduction by U.S. pharmaceutical wholesalers during the third quarter of 2003
18 following an equivalent inventory build during the second quarter of 2003.***

19 AmBisome® (amphotericin B) liposome for injection sales for the third quarter of
20 2003 were \$51.6 million, a record high and an increase of 6 percent compared to
21 the third quarter of 2002. Reported AmBisome sales in the third quarter of 2003
22 were \$6.1 million higher due to the favorable currency environment compared to
23 the same quarter last year. On a volume basis, AmBisome sales decreased by one
24 percent in Europe compared to the third quarter of 2002. Sales of Hepsera®
25 (adefovir dipivoxil 10 mg) totaled \$16.4 million for the third quarter of 2003, up
26 from \$12.4 million in the second quarter of 2003. Since the launch of Emtriva™
27 (emtricitabine) in July 2003, sales for the third quarter of 2003 were \$6.0 million.

28 (Emphasis added.)

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

27 196. A reasonable investor would consider Defendants' misrepresentations in their
28 July 14, 2003 press release, July 14, 2003 *Bloomberg News* statement, July 31, 2003 press

1 release, August 14, 2003 Form 10-Q, and October 28, 2003 press release as important in their
2 decision making and would have viewed these misrepresented facts as significantly altering the
3 total mix of information made available about Gilead from both a quantitative and qualitative
4 standpoint. Had Plaintiffs, and the other members of the Class, and the marketplace known of
5 Gilead's true financial condition and business prospects, Plaintiffs and other members of the
6 Class would not have purchased or otherwise acquired their Gilead securities, or, if they had
7 acquired such securities during the Class Period, they would not have done so at the artificially
8 inflated prices which they paid.

9 197. The market for Gilead's publicly traded securities was open, well-developed,
10 and efficient at all relevant times. As a result of Defendants' materially false and misleading
11 statements, Gilead's publicly traded securities traded at artificially inflated prices during the
12 Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired
13 Gilead publicly traded securities relying upon the integrity of the market price of Gilead's
14 publicly traded securities and market information relating to Gilead, and have been damaged
15 thereby, as evidenced by, among others, the stock price decline on or about October 28, 2003
16 when artificial inflation was released from Gilead stock.

17 198. At all relevant times, the material misrepresentations particularized in this
18 Complaint directly or proximately caused or were a substantial contributing cause of the
19 damages sustained by Plaintiffs and other members of the Class. As described herein, during
20 the Class Period, Defendants made or caused to be made a series of materially false or
21 misleading statements about Gilead's sales, business, product marketing and promotion,
22 prospects, operations and financial results. These material misstatements had the cause and
23 effect of creating in the market an unrealistically positive assessment of Gilead and its sales,
24 products, business, and operations and financial results, thus causing the Company's publicly
25 traded securities to be overvalued and artificially inflated at all relevant times. Defendants'
26 materially false and misleading statements during the Class Period resulted in Plaintiffs and
27 other members of the Class purchasing the Company's publicly traded securities at artificially
28 inflated prices, thus causing the damages complained of herein, as evidenced by, among others,

1 the stock price decline on or about October 28, 2003 when artificial inflation was released from
2 Gilead stock.

3 **ADDITIONAL SCIENTER ALLEGATIONS**

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

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

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

23 202. Importantly, the Individual Defendants were motivated to perpetuate the
24 fraudulent scheme and course of conduct described herein so that they could sell their
25 personally-held shares for gross proceeds of over \$20 million at artificially inflated prices.⁵

26 ⁵ In the Court's Amended Order Granting Defendants' 12(b)(6) Motion to Dismiss the
27 Consolidated Complaint, the Court ruled that Defendants' sales in and of themselves do not
28 show scienter. Figures outlining Defendants' sales are included here because when the
Complaint is viewed in its entirety, Defendants' sales further support the strong inference of

203. Within days after rebutting a Wall Street analyst's 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.

204. 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:

Date	Number of Shares Sold	Price Per Share	Total Value
08/08/2003	2,000	\$63.20	\$126,400
08/08/2003	12,500	\$63.15	\$789,375
08/08/2003	13,000	\$63.00	\$819,000
08/08/2003	22,500	\$62.28	\$1,401,300
TOTAL	50,000 (13.86% of stock and exercised options)		\$3,136,075

Mark L. Perry, Executive Vice President, Operations:

Date	Number of Shares Sold	Price Per Share	Total Value
08/05/2003	5,000	\$65.39	\$326,950
08/05/2003	5,000	\$65.20	\$326,000
08/05/2003	5,000	\$65.10	\$325,500
08/05/2003	5,000	\$65.05	\$625,250
08/05/2003	8,000	\$65.22	\$521,760
08/05/2003	14,344	\$65.00	\$932,360
08/06/2003	2,500	\$61.17	\$152,925
08/06/2003	2,500	\$62.00	\$155,000
08/06/2003	5,000	\$62.11	\$310,550

scienter raised in the Complaint and such sales also provide important context from which to view Defendants' fraudulent scheme.

TOTAL	52,344 (17.91% on 08/05/2003 and 4.90% on 08/06/2003 of stock and exercised options)		\$3,376,295
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John F. Milligan, Senior Vice President and CFO:

Date	Number of Shares Sold	Price Per Share	Total Value
08/07/2003	500	\$63.55	\$31,775
08/07/2003	5,000	\$63.30	\$316,500
08/07/2003	5,500	\$63.21	\$347,655
TOTAL	11,000 (20% of Stock and exercised options)		\$695,930

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

Date	Number of Shares Sold	Price Per Share	Total Value
08/05/2003	5,000	\$62.56	\$312,800
08/05/2003	10,000	\$63.28	\$632,800
08/05/2003	19,020	\$63.49	\$1,207,579.80
08/05/2003	21,000	\$63.35	\$1,330,350
08/28/2003	15,000	\$62.68	\$938,250
08/28/2003	20,000	\$62.55	\$1,253,600
TOTAL	90,020 (23.21% on 08/05/2003 and 16.12% on 08/28/2003 of stock and exercised options)		\$5,675,379.80

1 **Anthony Carraciolo, Senior Vice President, Manufacturing:**

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Date	Number of Shares Sold	Price Per Share	Total Value
08/11/2003	200	\$62.67	\$12,534
08/11/2003	500	\$62.64	\$31,320
08/11/2003	500	\$63.09	\$31,545
08/11/2003	1,100	\$62.68	\$68,948
08/11/2003	1,500	\$63.08	\$94,620
08/11/2003	24,500	\$62.66	\$1,535,170
08/11/2003	26,440	\$62.43	\$1,650,649.20
08/21/2003	100	\$65.73	\$6,573
08/21/2003	100	\$65.61	\$6,561
08/21/2003	400	\$65.71	\$26,284
08/21/2003	600	\$65.59	\$39,354
08/21/2003	700	\$65.62	\$45,934
08/21/2003	2,200	\$65.63	\$144,386
08/21/2003	2,800	\$65.72	\$184,016
08/21/2003	3,300	\$65.64	\$216,612
08/21/2003	3,500	\$65.65	\$229,775
08/21/2003	3,897	\$65.74	\$256,188.78
08/21/2003	4,800	\$65.60	\$314,880
08/21/2003	7,100	\$65.70	\$466,470
08/21/2003	10,900	\$65.68	\$715,912
08/21/2003	11,100	\$65.69	\$729,159
TOTAL	106,237⁶		\$6,806,890.98

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26 ⁶ There was insufficient information in Defendant Carraciolo's Form 4 filings with the

27 SEC to allow Lead Plaintiffs to calculate what percentage of stock and exercised options

28 Defendant Carraciolo sold during the Class Period. However, it is known that Defendant Carraciolo never sold any stock prior to the Class Period.

1 **William A. Lee, Senior Vice President, Research:**

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

13 206. Second, contrary to what Gilead disclosed in its Second Quarter 2003 Form
14 10-Q, the FDA Warning Letter was issued on July 29, 2003, not August 7, 2003. See Exhibit
15 E. Rather, the FDA Warning Letter was made public on August 7, 2003. The public disclosure
16 of the letter shines a bright light on the Individual Defendants' suspicious sales timing.
17 Specifically, Defendants Perry and Bischofberger sold *more than \$3,000,000* worth of stock
18 *each* between the date the FDA issued the FDA Warning Letter became public. Following suit,
19 Defendant Martin sold more than \$3,000,000 worth of stock on August 8, 2003. Third, and
20 equally troubling, the Individual Defendants sold their shares between \$61.17 to \$66.10 per
21 share, near the stock's peak at \$70.61 and prior to a low of \$50.27 on October 29, 2003.

22 207. Additionally, the Individual Defendants' prior trading history indicates that sales
23 during the Class Period were both unusual and suspicious. In no time prior to the Class Period
24 had all of the Individual Defendants ever sold stock during the same month. In fact, Defendant
25 Carraciolo *never* sold a single share of Gilead stock prior to the Class Period. However, during
26 a twenty-four day period in August 2003 the Individuals Defendants all sold significant
27 amounts of stock near the height of Gilead's artificially inflated share price for proceeds of
28 more than \$20 million.

1 208. The Individual Defendants' knowledge about the false and misleading
2 promotion of Viread, as evidenced by the Untitled FDA Letter and the FDA Warning Letter, as
3 well as their false and misleading statements concerning sales of Viread during Second Quarter
4 2003, highlight the unusual nature of Defendants' conspicuously well-timed stock sales.

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

19 **APPLICABILITY OF PRESUMPTION OF RELIANCE:**
20 **FRAUD-ON-THE MARKET DOCTRINE**

21 210. At all relevant times, the market for Gilead's publicly traded securities was an
22 efficient market for the following reasons, among others:

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

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

27 (c) Gilead regularly communicated with public investors via established
28 market communication mechanisms, including through regular disseminations of press releases

1 on the national circuits of major newswire services and through other wide-ranging public
2 disclosures, such as communications with the financial press and other similar reporting
3 services; and

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

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

14 **NO SAFE HARBOR**

15 212. The federal statutory safe harbor provided for forward-looking statements under
16 certain circumstances does not apply to any of the allegedly false statements pleaded in this
17 Complaint. Many of the specific statements pleaded herein were not identified as "forward-
18 looking statements" when made. To the extent there were any forward-looking statements,
19 there were no meaningful cautionary statements identifying important factors that could cause
20 actual results to differ materially from those in the purportedly forward-looking statements.
21 Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking
22 statements pleaded herein, Defendants are liable for those false forward-looking statements
23 because at the time each of those forward-looking statements was made, the particular speaker
24 knew that the particular forward-looking statement was false, and/or the forward-looking
25 statement was authorized and/or approved by an executive officer of Gilead who knew that
26 those statements were false when made. Moreover, to the extent that Defendants issued any
27 disclosures designed to "warn" or "caution" investors of certain "risks," those disclosures were
28 also false and misleading since they did not disclose that Defendants were actually engaging in

1 the very actions about which they purportedly warned and/or had actual knowledge of material
2 adverse facts undermining such disclosures.

3 **COUNT I**

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

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

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

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

25 216. In addition to the duties of full disclosure imposed on Defendants as a result of
26 their making of affirmative statements and reports, or participating in the making of affirmative
27 statements and reports to the investing public, they each had a duty to promptly disseminate
28 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*

1 *seq.*) and S-K (17 C.F.R. §229.10 *et seq.*) and other SEC regulations, including accurate and
2 truthful information with respect to the Company's operations, sales, product marketing and
3 promotion, financial condition and operational performance so that the market prices of the
4 Company's publicly traded securities would be based on truthful, complete and accurate
5 information.

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

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

21 219. Each of the Individual Defendants' primary liability, and controlling person
22 liability, arises from the following facts: a) each of the Individual Defendants was a high-level
23 executive and/or director at the Company during the Class Period; b) each of the Individual
24 Defendants, by virtue of his responsibilities and activities as a senior executive officer and/or
25 director of the Company, was privy to and participated in the creation, development and
26 reporting of the Company's internal sales and marketing plans, projections and/or reports; c)
27 each of the Individual Defendants enjoyed significant personal contact and familiarity with
28 each other and were advised of and had access to other members of the Company's

1 management team, internal reports, and other data and information about the Company's
2 financial condition and performance at all relevant times; and d) each of the Individual
3 Defendants was aware of the Company's dissemination of information to the investing public
4 which each knew or recklessly disregarded was materially false and misleading.

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

18 221. As a result of the dissemination of the materially false and misleading
19 information and failure to disclose material facts, as set forth above, the market prices of
20 Gilead's securities were artificially inflated during the Class Period. In ignorance of the fact
21 that market prices of Gilead's publicly traded securities were artificially inflated, and relying
22 directly or indirectly on the false and misleading statements made by Defendants, or upon the
23 integrity of the market in which the securities trade, and/or on the absence of material adverse
24 information that was known to or disregarded with deliberate recklessness by Defendants but
25 not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the
26 other members of the Class acquired Gilead securities during the Class Period at artificially
27 high prices and were damaged thereby, as evidenced by, among others, the stock price decline
28 on or about October 28, 2003 when artificial inflation was released from Gilead stock.

1 contend are false and misleading. Each of the Individual Defendants was provided with or had
2 unlimited access to copies of the Company's reports, press releases, public filings and other
3 statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements
4 were issued and had the ability to prevent the issuance of the statements or cause the statements
5 to be corrected.

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

10 228. As set forth above, Gilead and the Individual Defendants each violated Section
11 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of
12 their controlling positions, each of the Individual Defendants is liable pursuant to Section 20(a)
13 of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct,
14 Plaintiffs and other members of the Class suffered damages in connection with their purchases
15 of the Company's securities during the Class Period, as evidenced by, among others, the stock
16 price decline on or about October 28, 2003 when artificial inflation was released from Gilead
17 stock.

18 **PRAYER FOR RELIEF**

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

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

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

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

1 D. Such other and further relief as the Court deems appropriate.

2 **JURY TRIAL DEMANDED**

3 Plaintiffs hereby demand a trial by jury.

4 DATED: March 11, 2005

KAPLAN FOX & KILSHEIMER LLP

6 By: _____ /s/

7 Laurence D. King (SBN 206423)

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26 **Co-Lead Counsel for Plaintiffs**

1 **PROOF OF SERVICE**

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

5 On March 11, 2005, I served the following document(s):

6 **THIRD CONSOLIDATED AMENDED CLASS ACTION**
7 **COMPLAINT FOR VIOLATION OF FEDERAL**
8 **SECURITIES LAWS**

8 To the below parties:

9 Steven G. Schulman 10 Susan M. Greenwood 11 MILBERG WEISS BERSHAD & 12 SCHULMAN LLP 13 One Pennsylvania Plaza 14 New York, NY 10119 15 Telephone: 212-594-5300 16 Fax: 212-868-1229	Marc A. Topaz Chad E. Kauffman Richard A. Maniskas SCHIFFRIN & BARROWAY, LLP 280 King of Prussia Road Radnor, PA 19087 Telephone: 610-667-7706 Fax: 610-667-7056
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13 14 15 16 17	David A. Rosenfeld, Esq. LERACH COUGHLIN STOIA GELLER RUDMAN & ROBBINS LLP 200 Broadhollow Road, Suite 406 Melville, NY 11747 Telephone: 631-367-7100 Fax: 631-367-1173	Robert S. Green Robert A. Jigarjian John W. Pillette GREEN WELLING LLP 235 Pine Street, 15th Floor San Francisco, CA 94104 Telephone: 415-477-6700 Fax: 415-477-6710
18 19 20 21	Mel E. Lifshitz BERNSTEIN LIEBHARD & LIFSHITZ, LLP 10 East 40th Street, 22nd Floor New York, NY 10016-0201 Telephone: 212-779-1414 Fax: 212-779-3218	Marc M. Umeda ROBBINS UMEDA & FINK LLP 610 West Ash Street, Suite 1800 San Diego, CA 92101-3350 Telephone: 619-525-3990 Fax: 619-525-3991

23 XXX (BY FACSIMILE) I sent such document from facsimile machine on the above date. I
 24 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.

25 _____ (U.S. MAIL) I placed the sealed envelope(s) for collection and mailing by following
 26 ordinary business practices of Kaplan Fox Kilsheimer LLP. I am readily familiar with Kaplan
 27 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
 28 business, correspondence with postage fully prepaid is deposited with the United States Postal
 Service the same day as it is placed for collection.

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

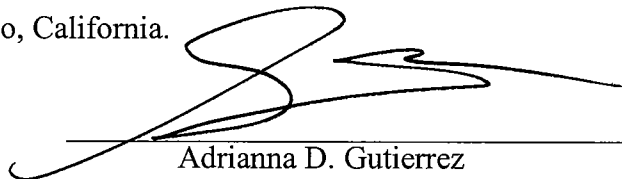
3 XXX (BY OVERNIGHT DELIVERY) I placed the sealed envelope(s) or package(s)
4 designated by the express service carrier for collection and overnight delivery by following the
5 ordinary business practices of Kaplan Fox Kilsheimer LLP. I am readily familiar with Kaplan
6 Fox Kilsheimer LLP's practice for collecting and processing of correspondence for overnight
7 delivery, said practice being that, in the ordinary course of business, correspondence for
8 overnight delivery is deposited with delivery fees paid or provided for at the carrier's express
9 service offices for next-day delivery the same day as the correspondence is placed for
10 collection.

11 On this date, pursuant to Civil L.R. 23-2, I served the above-listed document on the
12 Securities Class Action Clearinghouse via electronic mail at the following address:

13 Juan Carlos Sanchez
14 Securities Class Action Clearinghouse
15 Stanford University School of Law
16 Crown Quadrangle
17 Stanford, CA 94305-8612
18 jcarlos@law.stanford.edu

19 I declare under penalty of perjury under the laws of the United States of America and
20 the State of California that the foregoing is true and correct.

21 Executed March 11, 2005, at San Francisco, California.

22 
23 _____
24 Adrianna D. Gutierrez