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14 UNITED STATES DISTRICT COURT
15 NORTHERN DISTRICT OF CALIFORNIA
16

17 In re GILEAD SCIENCES SECURITIES)
LITIGATION)

MASTER FILE No. C-03-4999-MJJ

) CLASS ACTION

18)
19)
20 This Document Relates To:)
ALL ACTIONS.)

) **PLAINTIFFS' CORRECTED**
) **MEMORANDUM OF POINTS AND**
) **AUTHORITIES IN OPPOSITION TO**
) **DEFENDANTS' MOTION TO DISMISS**
) **THE FOURTH CONSOLIDATED**
) **AMENDED COMPLAINT**

) Date: February 14, 2006
) Time: 9:30 A.M.
) Dept.: Courtroom 11
) Judge: Honorable Martin J. Jenkins

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24)
25) Trial Date: None set
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1 **I. STATEMENT OF THE ISSUES**

2 1. Whether Plaintiffs sufficiently allege that Defendants are liable under Section 10(b)
3 of the Securities Exchange Act of 1934 (the “Exchange Act”).

4 2. Whether Plaintiffs sufficiently allege that Defendants are liable as control persons
5 under Section 20(a) of the Exchange Act.

6 **II. INTRODUCTION**

7 Plaintiffs’ Fourth Consolidated Amended Class Action Complaint dated December 2, 2005
8 (the “FAC”) satisfies the pleading requirements of the Private Securities Litigation Reform Act (the
9 “PSLRA”), the Exchange Act, and the Federal Rules of Civil Procedure.¹ The FAC describes how
10 Defendants’ off-label marketing scheme was a material fact that needed to be disclosed to investors
11 throughout the Class Period.² In sum, the FAC demonstrates that Defendants’ illegal off-label
12 marketing of Viread made Gilead’s Class Period statements false and misleading.

13 The FAC also alleges that the gradual partial revelation of Defendants’ off-label marketing
14 scheme caused Gilead to lose prescriptions and sales of Viread, as analysts pointed to “lower end-
15 user demand.” This lower end-user demand was in response to reprimands from the FDA, ultimately
16 causing Gilead’s stock price to drop and injuring the members of the Class. Nothing more is
17 required under the Rule 8 notice pleading standard for loss causation expressed by the Supreme
18 Court in *Dura Pharms., Inc. v. Broudo*, 125 S. Ct. 1627 (2005) and acknowledged by the Court in its
19 prior Order dismissing Plaintiffs’ Third Amended Class Action Complaint (the “TAC”). The FAC
20 should be sustained in its entirety and Defendants’ Motion to Dismiss should be denied.³

21 _____
22 ¹ Because the Court already has found that Plaintiffs adequately alleged Defendants engaged in and
23 had knowledge of Gilead Sciences, Inc.’s (“Gilead” or the “Company”) illegal off-label marketing of
Viread, Plaintiffs limit their arguments to new issues raised by Defendants with respect to the FAC.

24 ² Key details relating to Defendants’ off-label marketing activities are set forth in the FAC at ¶50
25 through ¶140. Unless otherwise indicated, “¶” refers to paragraphs of the FAC. In addition,
26 Defendants’ fraud was material because any investor would consider the fact that Gilead’s Viread
sales were built on illegal acts to be significant.

27 ³ Defendants have filed a new request for judicial notice that, in addition to seeking notice of
28 documents previously submitted to the Court, also seeks judicial notice of Gilead’s October 28, 2003
press release, certain analyst reports cited in the Complaint, and additional SEC filings that were not

1 **III. PROCEDURAL HISTORY**

2 In its October 11, 2005 order (the “Order”), the Court dismissed the TAC. The Court found
 3 that Plaintiffs “adequately alleged that Defendants engaged in an illegal off-label marketing scheme”
 4 and that it was “apparent that Plaintiffs have alleged sufficient facts to raise a strong inference that
 5 Defendants had knowledge of the company’s off-label marketing scheme.” (Order at 9.) The Court
 6 expressed concern regarding whether the TAC adequately alleged that Defendants’ “off-label
 7 marketing scheme affected Gilead’s sales figures during the second and third quarter of 2003 in a
 8 ‘material’ sense” and ultimately concluded that materiality was a “close question” that need not be
 9 decided because the TAC “failed to adequately allege loss causation.” (*Id.*) Although the Court
 10 acknowledged Plaintiffs’ theory that following disclosure of the FDA letters, physicians were less
 11 eager to prescribe Viread than they had been, the Court rejected it because it did not appear in the
 12 TAC, and because the Court believed Plaintiffs’ theory was inconsistent with Third Quarter growth
 13 in Viread prescriptions. *Id.* at 12 n.7. Plaintiffs filed the FAC on December 2, 2005 in response to
 14 the Court’s directives in the Order.

15 **IV. STATEMENT OF THE FACTS**

16 Plaintiffs respectfully refer the court to the FAC for a full recitation of the facts. Set forth
 17 below is a discussion of factual allegations in the FAC that address the loss causation and materiality
 18 concerns expressed by the Court and relate to Defendants’ new arguments on this motion.

19 **A. Defendants Engaged In an Off-Label Marketing Campaign to**
 20 **Illegally Boost Gilead’s Sales of Viread**

21 Defendants’ marketing plan for Viread always included aggressive promotion beyond
 22 Viread’s FDA-approved Package Labeling. Following Viread’s approval in October 2001, Gilead
 23 immediately trained, directed, and expected its employees to use off-label information to increase
 24 their sales of the drug. (*See, e.g.*, ¶¶69-77, 79-84, 87-90.)

25
 26 cited or referenced in the Complaint. As Plaintiffs argued in their previous Response to Defendants’
 27 Request for Judicial Notice, though Federal Rule of Evidence 201 permits this Court to notice these
 28 documents for their contents, they may not be noticed for their truth.

1 Defendants' egregious violations of FDA rules and regulations did not go unnoticed. Indeed,
 2 the FDA twice, in a March 14, 2002 letter (the "Untitled FDA Letter) and again in a July 29, 2003
 3 cease and desist directive to Gilead (the "FDA Warning Letter"), condemned Gilead's off-label
 4 marketing practices and ordered Gilead to stop.⁴ (¶¶78, 91-121, 125-33.) Although it was issued on
 5 July 29, 2003, the FDA Warning Letter was not made public by the FDA until August 7, 2003.⁵
 6 (¶¶125, 182, 190-91.) Defendants chose not to disclose the FDA Warning Letter until August 14,
 7 2003, when Gilead mentioned it in passing in its Second Quarter 2003 Form 10-Q. (¶199.)

8 **B. Defendants' Off-Label Marketing Resulted in Increased Sales of**
 9 **Viread in the Second Quarter of 2003**

10 Defendants' continued off-label marketing of Viread had its intended effect: Gilead sold
 11 more Viread as physicians prescribed more of it, often for purposes other than those approved by the
 12 FDA, and often based on Gilead's lies about the true safety profile of the drug. (¶¶141, 158-59.)
 13 Defendants provided so much off-label material and were so forceful in instructing sales
 14 representatives to utilize off-label information that 75% to 95% of Viread sales arose from off-label
 15 promotion. (¶¶141-65.)

16 Gilead sales representatives' off-label marketing took three forms: (1) marketing to HIV
 17 patients co-infected with Hepatitis B virus ("HBV"); (2) marketing Viread as a first-line or initial
 18 therapy for HIV infection prior to its approval for such use; and (3) marketing against Viread's
 19 safety profile.⁶ (¶¶141-65.) Defendants' trifecta of off-label marketing comprised 75% to 95% of
 20

21
 22 ⁴ Off-label marketing statements were made by Defendant Martin and it was company-wide
 knowledge that Martin was the cause of the Untitled FDA Letter. (¶78.)

23 ⁵ This Court's Order mistakenly stated that Gilead revealed the FDA Warning Letter to the public on
 24 August 7, 2003. (Order at 3 n.1.) In fact, the letter was made public by the FDA on that date.
 (¶199.)

25 ⁶ In response to Defendants' illegal off-label marketing to co-infected HBV patients, the percentage
 26 of co-infected patients using Viread rose significantly from pre-Class Period amounts, materially
 27 increasing Viread sales. (¶¶152-54.) Defendants also materially increased Viread sales by
 28 improperly marketing it as a first-line therapy prior to the FDA's approval of Viread in "treatment
 naïve" patients. (¶¶155-57.) Finally, physicians and HIV practitioners across the country, in
 response to off-label marketing that Viread had no side effects and was as safe as placebo, wrote

1 Viread sales, causing tremendous growth from its launch through the Second Quarter 2003. (¶¶160-
2 65, 197.) As a result of illusory demand for the drug and misinformation regarding the reasons for
3 increased demand created by the off-label marketing scheme, investors not only overestimated
4 Viread's potential, but wholesalers overstocked the drug in the Second Quarter 2003 in anticipation
5 of continued high sales. (¶¶7, 9, 10, 171.)

6 **C. Defendants' False and Misleading Statements Sustained the Illusion**
7 **of Increased Demand for Viread and Caused Plaintiffs' Losses**

8 Defendants misled the market about the demand for Viread through their extensive off-label
9 marketing. This allowed Gilead to report extraordinary growth for sales of Viread, (¶¶149-50, 197),
10 and led investors and wholesalers to believe that sales would continue to increase. (*See, e.g.*, ¶¶166-
11 73.) Thus, the wholesaler overstocking was also caused by Defendants' illegal off-label marketing
12 scheme. (¶171.) Because the extent of Defendants' off-label scheme remained unknown, analysts
13 following Gilead were blinded by supposed strong demand for Viread and were thus unconcerned
14 with the amount of Viread that wholesalers were overstocking. (¶¶185-88.) Market analysts and
15 investors did not know that Gilead's reported results, including the wholesaler overstocking, were
16 based on artificially inflated demand caused by an illegal marketing scheme. (¶189.) Early in the
17 Third Quarter of 2003, the FDA Warning Letter to Gilead became public. (¶191.) Although
18 investors were aware of the letter, they were unaware of the extent to which Gilead's entire business
19 depended on illegal marketing, and did not attribute much significance to it. (¶¶191-95.)

20 Unbeknownst to the market, disclosure of the FDA Warning Letter negatively effected
21 Viread sales. Physicians, now alerted to Gilead's illegal marketing scheme and to potential safety
22 problems with Viread, were less eager to prescribe the drug to their patients. (¶200.) Competitors
23 were also able to use Defendants' illegal scheme as a promotional tool for competing drugs. (*Id.*)
24 Following publication of the FDA Warning Letter, Gilead saw a marked drop in August 2003 in

25
26
27 prescriptions for Viread, materially increasing Gilead's Viread sales and the appearance of demand.
(¶¶158-59.)

1 prescriptions and sales of Viread, and flattened growth for the rest of the Third Quarter. (¶201.)⁷
 2 The disclosure of the FDA Warning Letter resulted in weakened sales and prescriptions that did not
 3 demonstrate the artificially inflated strong growth Defendants touted and investors expected. (¶203.)

4 The Viread demand problems, coupled with the drop in sales and prescriptions, influenced
 5 wholesalers to draw down much more of their excess inventory than they otherwise would have.
 6 (¶204.) On October 28, 2003, Defendants issued a press release revealing that Viread sales for the
 7 Third Quarter would be materially less than expected -- expectations raised by the market's false
 8 impression of Viread demand. The combination of the disclosure of the FDA Warning Letter and
 9 the disclosure of disappointing sales in the October 23, 2003 press release revealed Gilead's true
 10 financial circumstances. The market was stunned. Analysts noted that wholesale stocking levels
 11 had reached all time lows and lowered their fourth quarter 2003 projections based on "lower end-
 12 user demand." (¶¶206-08.) This revelation caused Gilead's stock to fall 12%, or \$7.46 per share,
 13 from a high of \$59.46 per share on October 28, 2003 to a low of \$50.27 and closing at \$52.00 per
 14 share on October 29, 2003. (¶208.) The shocking news also sparked enormous trading volume of 66
 15 million Gilead shares compared to the average daily volume of 4.6 million shares – a 1,400%
 16 increase. (¶208.) Reasonable investors would (and did, as evidenced by the soaring trading volume)
 17 consider Defendants' misrepresentations as important in their decision-making. (¶209.)

18 **V. ARGUMENT**

19 **A. Relevant Standards**

20 In considering a Motion to Dismiss, "[a]ll allegations of material fact made in the complaint
 21 are taken as true and construed in the light most favorable to the plaintiff." *No. 84 Employer-*
 22 *Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 931 (9th Cir.
 23 2003) ("*Am. West*").⁸ The FAC must be examined in its entirety, as "individual pieces of evidence,

24
 25 ⁷ The exact sales and prescription figures are exclusively in the possession of Defendants and certain
 26 third party organizations that track prescription drug sales, and are not available to Plaintiffs for use
 at this stage of litigation.

27 ⁸ Internal citations and footnotes are omitted, and emphasis is added, unless otherwise noted.

1 insufficient in themselves to prove a point, may in cumulation prove it. The sum of an evidentiary
 2 presentation may well be greater than its constituent parts.” *Bourjaily v. U.S.*, 483 U.S. 171, 179-80
 3 (1987); *see also Nursing Home Pension Fund v. Oracle Corp.*, 380 F.3d 1226, 1230 (9th Cir. 2004).⁹
 4 “Moreover, a complaint should not be dismissed unless a plaintiff could prove no set of facts in
 5 support of his claim that would entitle him to relief.” (Order at 5 (citing *Parks Sch. of Bus., Inc. v.*
 6 *Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995)); *see also Conley v. Gibson*, 355 U.S. 41, 45-46
 7 (1957).

8 **B. Gilead’s Misrepresentations Regarding Off-Label Marketing and the**
 9 **Impact of Off-Label Marketing Were Material**

10 The Court did not reach a conclusion as to whether Plaintiffs established a connection
 11 between the Company’s off-label marketing practices and the 2003 Second Quarter reports alleged
 12 to be false and misleading. (*See* Order at 9-10.) Specifically, the Court reasoned that it was a “close
 13 question” whether Plaintiffs demonstrated that the off-label marketing scheme was a material fact
 14 that needed to be disclosed to investors along with Gilead’s financial results. (*Id.* at 10.)

15 **1. Materiality is a Highly Fact-Specific Issue that Generally**
 16 **Should Not be Decided on a Motion to Dismiss**

17 Defendants are liable under § 10(b) and Rule 10b-5 if they made misstatements a reasonable
 18 investor would consider in deciding whether to buy Gilead’s stock. *See Immune Response*, 375 F.
 19 Supp. 3d at 1020.¹⁰ “[A] fact is material if there is a ‘substantial likelihood’ that a reasonable
 20 investor would consider it important in his or her decision making.” *Id.* (quoting *Am. West*, 320
 21 F.3d at 934). Materiality determinations “‘require[] delicate assessments’ of the inferences a

22
 23 ⁹ “Even if the face of the pleadings indicate[s] that recovery is very remote and unlikely, Plaintiffs
 24 are still entitled to offer evidence in support of their claims.” *In re Immune Response Secs. Litig.*,
 25 375 F. Supp. 2d 983, 1015 (S.D. Cal. 2005). In particular, “[w]hether a statement is misleading
 and whether adverse facts are adequately disclosed are generally questions that should be left to the
 trier of fact.” *Id.* at 1021.

26 ¹⁰ An immediate market reaction is not required to find that misrepresentations or omissions are
 27 material. *Am. West*, 320 F.3d at 934 (rejecting “bright line” materiality test). Further, the PSLRA
 does not change traditional pleading rules with respect to materiality. *See Gebhardt v. ConAgra*
Foods, Inc., 335 F.3d 824, 830 n.3 (8th Cir. 2003). Rule 8 still governs the pleading of materiality.

1 ‘reasonable shareholder’ would draw from a given set of facts and the significance of those
 2 inferences to him, and these assessments are peculiarly ones for the trier of fact.” *Fecht v. Price Co.*,
 3 70 F.3d 1078, 1080-81 (9th Cir. 1995); *Am. West*, 320 F.3d at 934.¹¹

4 Defendants contend this action should be dismissed based on Plaintiffs’ failure to adequately
 5 plead materiality – *i.e.*, that Defendants’ off-label marketing scheme had a material impact on
 6 Gilead’s finances. (Defs. Br. at 17.) During the Class Period, Viread was Gilead’s premier product,
 7 comprising 65% of the Company’s total revenues – its sales were the most important measurement
 8 of Gilead’s performance, and analysts and investors looked to such sales to gauge whether Gilead’s
 9 business was on track and growing. (¶¶2, 4.) The fact that Defendants orchestrated and encouraged
 10 illegal marketing, misled the public as to the cause of 75% to 95% of all domestic Viread sales, and
 11 were admonished twice by the FDA, would have been material to a reasonable investor. *See Am.*
 12 *West*, 320 F.3d at 934-35.¹² Investors would rightly be concerned that the cornerstone of Gilead’s
 13 business was an illegal off-label marketing scheme, that demand for Viread was artificially inflated,
 14 and that Gilead would be censured for its behavior, thus affecting sales and end user demand – as
 15 actually occurred. (¶¶206-09.) Additionally, unaware that Viread sales were driven by off-label
 16 marketing, investors might overestimate the future prospects of the Company, wrongly expecting an
 17 increase in sales once Viread was approved for broader indications.

18 Defendants have not shown that the issue of materiality can be decided as a matter of law.
 19 The facts alleged raise an issue for trial. By concealing the source of 75%-95% of domestic Viread
 20 sales, Defendants materially misled investors about Gilead’s prospects and stock price. *See Am.*
 21 *West*, 320 F.3d at 935 (“reasonable investor would find significant the information regarding a

23 ¹¹ “In other words, materiality depends on the significance the reasonable investor would place on
 24 the withheld or misrepresented information.” *Immune Response*, 375 F. Supp. 3d at 1021.
 25 Materiality determinations are particularly suited for the trier of fact, and this presumption can *only*
 26 be overcome if the omitted fact, taking into consideration all of the circumstances, is so obviously
 27 immaterial that reasonable minds could not differ. *Am. West*, 320 F.3d at 934; *see also Basic, Inc. v.*
 28 *Levinson*, 485 U.S. 224, 231-32 (1988).

¹² *See also Immune Response*, 375 F. Supp. 2d at 1021 (materiality met where “Plaintiffs allege that
 Defendants’ misstatements of fact formed a false basis for its investors’ perceptions.”)

1 company's deferred maintenance costs, unsafe maintenance practices, and possible sanction . . . and
 2 would consider the potential effects of each of these facts on the *overall economic health of the*
 3 *company* as 'significantly altering' the 'total mix' of information made available.'").

4 **2. The FAC Adequately Alleges the Off-Label Marketing Scheme**
 5 **Resulted in Materially Artificially Inflated Sales and Demand**
 6 **for Viread, Including During the Second Quarter of 2003**

6 The FAC addresses the Court's materiality concerns head-on, specifically identifying how
 7 Defendants' illegal scheme increased demand for and sales of Viread by 75%-95%, including during
 8 the Second Quarter of 2003. (¶¶141-65.) Plaintiffs sufficiently plead a connection between
 9 Defendants' off-label marketing, sales of Viread, and the Company's 2003 Second Quarter reports.¹³

10 The FAC delineates the substantial amounts of Viread sold off-label, describes the specific
 11 data that forms the basis of those percentages, and applies those percentages to articulate well-
 12 grounded estimates of how much Defendants' off-label marketing inflated Gilead's overall revenues
 13 and sales figures for Viread, including during the second quarter of 2003.¹⁴ The allegations of the
 14 FAC also detail how the off-label marketing scheme was taught at all levels of the Company,
 15 including at national and regional meetings, and that it uniformly inflated Gilead's Viread sales
 16 numbers and demand for the drug.¹⁵

18 ¹³ Plaintiffs' conclusions are based on several sources of data, which focused on the three types of
 19 off-label marketing: (1) marketing to HBV co-infected HIV patients; (2) marketing Viread for
 20 treatment "naïve" patients prior to FDA approval for such use; and (3) marketing against Viread's
 safety profile. (*See, e.g.*, ¶¶144, 148.)

21 ¹⁴ (*See, e.g.*, ¶144 (approximately 85% to 95% of CW1's \$3 million in Viread sales arose from off-
 22 label promotion); ¶148 (approximately 85% to 90% of CW2's \$25 to \$35 million in Viread sales
 23 were a result of off-label marketing); ¶152 (AIDS-specialist treating between 2,000 and 2,500 AIDS
 24 patients routinely prescribed Viread off-label and received unsolicited off-label data from Gilead);
 25 ¶156 (infectious disease specialists received unsolicited off-label advice on using Viread as a first-
 line therapy and wrote prescriptions as a result); ¶158 (medical director of large AIDS clinic wrote
 prescriptions for Viread based on false and misleading sales pitches concerning Viread's safety
 profile.))

26 ¹⁵ These facts explain and sufficiently allege that the illegal Viread marketing led to massive
 27 amounts of increased Viread prescriptions and sales, and gave the market expectations of additional
 28 rapid growth. In fact, Defendant Martin, in a *Forbes* article, admitted that, to reach its goal of
 increased prescriptions, Gilead had to use marketing to convince physicians to switch patients to
 Viread. (¶6.) The increase in Viread prescriptions (albeit artificially inflated due to off-label

1 Further, CW1's and CW2's experiences at numerous national meetings, in addition to CW1's
2 experiences on Gilead's elite Field Marketing Advisory Committee ("FMAC"), support the
3 conclusion that their off-label experiences were not regionally isolated. (¶¶41, 60-66, 69-77, 104-06,
4 110-11, 116-17, 119-22, 151.) Indeed, the FMAC was comprised of a select committee of Gilead
5 sales and marketing staff from various regions of the country, as well as high-ranking Gilead
6 officers, that met periodically to engage in frank discussions regarding theories and strategies for
7 selling Viread. (¶¶41, 87-88, 102-03, 113.) At the intimate FMAC meetings, CW1 was exposed to
8 other Therapeutic Specialists and Gilead executives from all regions of the United States who would
9 discuss what illegal off-label sales tactics worked best to sell Viread. (¶¶87-88, 102-03, 113.) From
10 these meetings, CW1 was able to estimate with reasonable certainty that other Gilead sales people
11 sold material amounts of Viread as a result of off-label marketing.¹⁶

12 CW1's and CW2's accounts of the significant details of Defendants' systematic and
13 pervasive off-label marketing scheme and how that scheme was implemented at numerous national
14 and regional meetings strongly suggest that their experiences at Gilead were neither atypical nor
15 uncommon, and that neither CW1 nor CW2 was "regionally isolated," such that their experiences
16 should not be extrapolated throughout the Company. (¶138.)

17 Despite the foregoing, Defendants incorrectly assert that "plaintiffs fail to provide an
18 adequate basis" for making an inference that off-label marketing accounted for 75% to 95% of all
19 Viread sales. (Defs. Br. at 17.) First, Defendants' argument ignores most of Plaintiffs' allegations,
20 including that a Medical Director of a large AIDS clinic in Washington, D.C. wrote numerous
21 prescriptions for Viread *based on false representations by Gilead marketing representatives* – the
22 same representations identified as illegal in the FDA's letters to Gilead. (¶158.) The combination of
23

24 marketing) was an important product demand indicator. Defendant Martin admitted as much in
25 Gilead's October 28, 2003 press release. (¶5.)

26 ¹⁶ Although CW2 was not a member of the FMAC, CW2 did attend numerous national and regional
27 meetings where CW2 received the same directives as all other Viread sales people – to sell Viread
28 with illegal, off-label information. (¶¶48, 60-62, 69-77, 79, 83, 89, 104-06, 110-111, 114, 116-17,
119-22.)

1 first-person accounts of the confidential witnesses and health care practitioners, along with the FDA
2 letters, combine to bolster the allegations that off-label marketing resulted in material sales.

3 Second, Defendants once again attempt to sever the link between their off-label marketing
4 and actual off-label prescriptions by citing an *Annals of Health Law* article for the proposition that
5 “researchers estimate that 40 to 60 percent of the prescriptions written each year are for ‘off-label’
6 uses and that this is particularly common for AIDS, cancer, rare diseases and pediatric uses.” (Defs.
7 Br. at 18.) However, the FAC alleges an explosive growth in off-label sales coupled with Gilead’s
8 aggressive off-label marketing scheme. (¶149.) It is a reasonable and justifiable inference that the
9 growth in off-label prescriptions was directly tied to the marketing, particularly where, as here, the
10 combination of specific witnesses and third party data corroborate that particular prescriptions were
11 based on off-label marketing. (¶¶151-52, 156, 158-65.) Indeed, it is difficult to imagine what else
12 Defendants’ would have the Plaintiffs do – short of actually interviewing every doctor who ever
13 prescribed Viread.¹⁷ The statistical evidence of off-label prescriptions (¶¶154-65), coupled with
14 extensive descriptions of off-label marketing, supplemented with the personal accounts of
15 salespersons and physicians, and the FDA letters, are more than sufficient, at the pleadings stage, to
16 raise an inference that material amounts of Viread sales and prescriptions resulted from Defendants’
17 off-label sales pitches.¹⁸ To the contrary, the inferences that Defendants urge upon the Court are
18 nothing short of bizarre: Defendants would have this Court conclude that despite Plaintiffs’
19 allegations of a pervasive, illegal marketing scheme, designed by the Company’s top officials and
20 rigidly enforced for a period of years, the scheme had virtually *no* effect on physician’s prescribing
21 patterns. Apparently, Defendants would have this Court accept that they went to such trouble to

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23 ¹⁷ As recognized by the Court previously, Plaintiffs are not required to detail the impact of Gilead’s
24 off-label marketing on a sale-by-sale basis.

25 ¹⁸ Indeed, in the case of *U.S. v. Parke-Davis, Division of Warner-Lambert Co.*, 147 F. Supp. 2d 39,
26 49 (D. Mass. 2001), the government charged that the defendants’ illegal off-label marketing scheme
27 caused physicians to write prescriptions that were submitted to Medicaid and the Veterans
28 Administration. The government sought reimbursement for each improper off-label prescription.
The court rejected the defendants’ argument that the complaint would fail unless it identified each
improper prescription. If a case seeking reimbursement need not identify each off-label prescription
in the complaint, then surely a case charging only the existence of false statements need not do so.

1 increase sales without ever noticing that their efforts were entirely unnecessary.

2 Taking the collective allegations of the FAC as true, it is clear that the Court should draw an
3 inference that Gilead's company-wide Viread sales were materially artificially inflated as a direct
4 result of the ongoing and pervasive off-label marketing of the Company's premiere product. (¶163.)
5 The inference that Gilead's Viread sales were materially artificially inflated by off-label marketing is
6 supported by: (1) the intensity and frequency with which Gilead ordered its sales force to use off-
7 label marketing to sell Viread; (2) the pressure put on CW1 and CW2 to actually utilize off-label
8 marketing; (3) the volume of CW1 and CW2 Viread sales caused by off-label marketing; (4) the
9 FDA letters, which evidence that sales people other than CW1 and CW2 were illegally marketing
10 Viread consistent with Defendants' directives; (5) the statistical evidence of the levels of off-label
11 sales; and (6) the familiarity that CW1 and CW2 had with other Gilead sales people and their
12 knowledge that other Gilead sales people used off-label marketing to sell Viread. (¶164.)

13 Growing Vired sales and demand meant growth and strong financial results for Gilead which,
14 in turn increased the value of Gilead stock and investor expectations. (*See, e.g.*, ¶¶4, 9, 11.)
15 Gilead's off-label marketing scheme directly and materially distorted Gilead's financials, however,
16 creating the false appearance that Gilead's sales were strong because of naturally occurring, demand-
17 driven increases in prescriptions, and failed to disclose that the true driving force behind the
18 increased prescriptions was Defendants' FDA-condemned illegal acts. (¶¶8-9.)

19 The Court already determined that Plaintiffs alleged sufficient facts in the TAC to raise a
20 strong inference that Defendants had knowledge of Gilead's off-label marketing scheme. A
21 reasonable investor would consider Defendants' misrepresentations and omissions in their July 14,
22 2003 press release, July 13, 2003 *Bloomberg News* statement, July 31, 2003 press release, August
23 14, 2003 Form 10-Q, and October 28, 2003 press release as important in their decision making and
24 would have viewed these misrepresented facts as significantly altering the total mix of information
25 made available about Gilead from both a quantitative and qualitative standpoint. (¶209.) Even if the
26 Court, given the totality of the allegations in the FAC, still views materiality as a "close question,"
27 such a "close question" should be resolved in favor of Plaintiffs at the pleading stage.

28

1 **3. Defendants Were Required to Disclose their Off-Label**
 2 **Marketing Scheme to Investors**

3 In a footnote, Defendants cite *In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 400-02 (6th
 4 Cir. 1997) for the proposition that their illegal marketing campaign did not create, and thus they did
 5 not breach, a duty to disclose. (*See* Def. Br. at 17, n.11). Unlike the allegations here, the plaintiffs
 6 in *Sofamor* did not allege a systematic, illegal promotional scheme twice condemned by the FDA as
 7 illegal and controlled at the highest levels of the company that generated between 75%-95% of all
 8 sales of the company’s marquee product.

9 If Defendants’ argument is taken to its logical conclusion, then even if 100% of a company’s
 10 sales are caused by illegal and fraudulent conduct, disclosure would not be required. Such a result
 11 would be untenable. Defendants affirmatively misrepresented Gilead’s revenues by including the
 12 illegal off-label sales and created an artificially high demand for Viread that investors expected to
 13 continue.¹⁹ Once a company speaks affirmatively, it must speak fully to ensure the market is not
 14 misled. *Helwig v. Vencor, Inc.*, 251 F.3d 540, 560-61 (6th Cir. 2001) (en banc).

15 **C. The FAC Adequately Pleads Loss Causation**

16 In *Dura*, the Supreme Court examined the element of loss causation in securities fraud cases.
 17 The Court held that loss causation requires that the plaintiff “prove that the defendant’s
 18 misrepresentation (or other fraudulent conduct) proximately caused the plaintiff’s economic loss.”
 19 *Id.* at 1633; *see also Bastian v. Petren Resources Corp.*, 892 F.2d 680, 686 (7th Cir. 1990) (cited
 20 with approval in *Dura*, 125 S.Ct. at 1633) (describing “loss causation” as “just an exotic name” for
 21 the “standard requirement” of proximate cause). In other words, the plaintiff must show that he or
 22 she suffered some economic harm as a result of the fraud, in contrast to the Ninth Circuit’s prior rule
 23 that permitted a claim to proceed merely upon allegations that stock was purchased at artificially
 24 inflated prices. *See Dura*, 125 S.Ct. at 1633. In setting this standard, the Court explicitly invoked
 25 traditional common law notions of causation. *See id.* at 1632-33.

26 ¹⁹ Investors, unaware of the scheme, were under the false impression that Gilead’s marketing – and
 27 thus Viread sales – were reasonably consistent with the labeling. This false impression left investors
 28 with an entirely fictional picture of the drug, the market for the drug, and the drug’s future potential.

1 The Court then turned to the issue of how causation must be pled in a complaint, and
2 declined to adopt or recognize any heightened pleading standard for loss causation. Instead, it
3 expressly invoked the “simple test” of Rule 8 pleading standards and held that “it should not prove
4 burdensome for a plaintiff who has suffered an economic loss to provide a defendant with some
5 indication of the loss and the causal connection that the plaintiff has in mind.” *Id.* at 1634; *see also*
6 *In re Daou Sys.*, 411 F.3d 1006, 1026 (9th Cir. 2005) (quoting *Dura*; complaint need only provide
7 “some indication” of the connection between the fraud and the loss). Thus, Defendants are simply
8 wrong when they argue that there is a “high bar” for pleading loss causation (Defs. Br. at 10), for the
9 Supreme Court was explicit in holding that pleading loss causation “should not be burdensome.”
10 The Court’s opinion has been widely interpreted to mean that plaintiffs need only plead the element
11 of loss causation in accord with the requirements of Rule 8. *See, e.g., DH2, Inc. v. Athanassiades*,
12 2005 U.S. Dist. LEXIS 32792, at *38 (N.D. Ill. Dec. 14, 2005); *In re NYSE Specialists Sec. Litig.*,
13 2005 U.S. Dist. LEXIS 32597, at *84 (S.D.N.Y. Dec. 12, 2005); *In re CMS Energy Secs. Litig.*, 2005
14 U.S. Dist. LEXIS 31576, at *13 (E.D. Mich. Dec. 7, 2005); *Greater Pa. Carpenters Pension Fund v.*
15 *Whitehall Jewellers, Inc.*, 2005 U.S. Dist. LEXIS 12971, at *16 (N.D. Ill. June 30, 2005).

16 Defendants offer two challenges to the loss causation allegations in the FAC. First,
17 Defendants argue the *theory* of loss causation alleged in the FAC does not, as a *legal matter*, satisfy
18 the element of loss causation for a securities fraud claim. (Defs. Br. at 8-13.) Second, Defendants
19 argue that even if the theory of loss causation set forth in the FAC is legally sufficient, Plaintiffs
20 have not alleged sufficient *facts* to support their theory. (Defs. Br. at 13-14.) In so arguing,
21 Defendants evidence their obvious understanding of Plaintiffs’ loss causation allegations and the
22 connection between the economic harm suffered by Plaintiffs and the alleged fraud. Therefore,
23 merely by demonstrating their comprehension of Plaintiffs’ claims, Defendants established that
24 Plaintiffs have “provide[d] the defendants with notice of [] the relevant economic loss [and] the
25 causal connection ... between that loss and the misrepresentation....” *Dura*, 125 S.Ct. at 1634.
26 Thus, the FAC properly alleges that the fraud caused Plaintiffs’ losses, passing *Dura*’s “simple test.”

27
28

1 **1. The Theory of Loss Causation Set Forth in the FAC Satisfies**
2 ***Dura***

3 *Dura* equated the loss causation inquiry with the traditional tort concept of proximate cause.
4 See *Dura*, 125 S.Ct. at 1633. In any proximate cause inquiry, the question is whether the “injury was
5 the natural and probable consequence of the negligence or wrongful act” and “whether it ought to
6 have been foreseen in the light of the attending circumstances.” *Brady v. Southern Ry. Co.*, 320 U.S.
7 476, 483 (1943); *Ideal Steel Supply Corp. v. Anza*, 373 F.3d 251, 257 (2d Cir. 2004) (an act is the
8 proximate cause of an injury where it was a “substantial factor in the sequence of responsible
9 causation,” and where the injury is “reasonably foreseeable or anticipated as a natural
10 consequence”). Conversely, there is no proximate causation if investors’ losses are associated with
11 an “intervening event” that was unrelated to the fraud. *Emergent Capital Inv. Mgmt., LLC v.*
12 *Stonepath Group, Inc.*, 343 F.3d 189, 197 (2d Cir. 2003) (cited with approval in *Dura*, 125 S. Ct. at
13 1632-1633); *Castellano v. Young & Rubicam, Inc.*, 257 F.3d 171, 190 (2d Cir. 2001) (intervening
14 events are “external and unforeseeable factors” unrelated to the fraud); see also *U.S. v. Hicks*, 217
15 F.3d 1038, 1048-49 (9th Cir. 2000). As the *Restatement (Second) of Torts* (1977) describes it in a
16 section relied upon by the *Dura* Court, “[T]here is no liability when the value of the stock goes down
17 after the sale, not in any way because of the misrepresented financial condition, but as a result of
18 some subsequent event that has no connection with or relation to its financial condition.”
19 *Restatement (Second) of Torts*, § 548A cmt b; cf. *In re TyCom Ltd. Sec. Litig.*, 2005 U.S. Dist.
20 LEXIS 19154, at *44 n.15 (D.N.H. Sept. 2, 2005) (loss causation exists because the event that led
21 the stock price collapse was “not an intervening event, but rather the proximate result of defendants’
22 misrepresentation”).

23 Proximate cause exists when a stock price drop occurs after *falsity* is disclosed – for instance,
24 where there is a restatement or an admission of prior misstatements – or when a stock price drop
25 follows disclosure of the “true facts” that had been concealed by the fraud, even if there is no
26 disclosure that prior statements had actually been false. (Defs. Br. at 10); see also *In re Omnivision*
27 *Tech.*, 2005 U.S. Dist. LEXIS 16009, at *18-19 (N.D. Cal. July 29, 2005). These are *not*, however,
28 the only methods by which proximate cause may be established. That is, there is no requirement in

1 the traditional proximate cause inquiry that requires every fraud case to exhibit the classic pattern of
2 disclosure (whether of falsity or of previously-concealed facts) followed by an immediate price drop.
3 *In re Parmalat Sec. Litig.*, 375 F. Supp. 2d 278, 305 (S.D.N.Y. 2005) (“An allegation that a
4 corrective disclosure caused the plaintiff’s loss may be sufficient to satisfy the loss causation
5 requirement. It is not, however, necessary.”); *In re Loewen Group Inc. Secs. Litig.*, 2005 U.S. Dist.
6 LEXIS 23841, at *16-17 (E.D. Pa. Oct. 18, 2005) (same). Rather, proximate cause exists so long as
7 the “risk that caused the loss was within the zone of risk concealed by the misrepresentations and
8 omissions alleged by a disappointed investor.” *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173
9 (2d Cir. 2005). Nor need losses occur immediately; on many occasions, losses accumulate over time
10 as the market gradually becomes aware of the underlying facts. *See, e.g., TyCom*, 2005 U.S. Dist.
11 LEXIS 19154, at *42; *Danis v. USN Communs., Inc.*, 73 F. Supp. 2d 923, 943 (N.D. Ill. 1999)²⁰. In
12 other words, the complaint need not allege that the market directly reacted to any particular
13 disclosure at all, so long as the complaint alleges “a causal connection between the concealed
14 information . . . and the ultimate failure of the venture.” *Emergent Capital*, 343 F.3d at 198.²¹

15 Whether the Court analyzes the sufficiency of Plaintiffs’ loss causation allegations in terms
16 of the disclosure of “relevant truth” or via the traditional proximate cause principle of foreseeability,
17 Defendants’ Motion to Dismiss must be denied because the FAC puts Defendants on notice of the
18 causal connection between Defendants’ off-label marketing and the decline in stock price at the
19 close of the Class Period.

20 Specifically, contrary to Defendants’ assertions, *Dura* does not require Plaintiff to allege a
21 “corrective disclosure” by Defendants in order for the FAC to satisfy the Rule 8 pleading
22 requirements for loss causation. That is not the holding in *Dura* or the law in the Ninth Circuit. The
23 Supreme Court in *Dura* declined to adopt the argument that fraud can only be revealed by a

24
25 ²⁰ *Danis* followed the Seventh Circuit standard for loss causation, which was also approved by the
Supreme Court. *See Dura*, 125 S.Ct. at 1633 (citing *Bastian*, 892 F.2d 680).

26 ²¹ While the *Dura* Court referred to the “relevant truth” eventually causing a loss, *see Dura*, 125
27 S.Ct. at 1631-32, it in no way jettisoned ordinary proximate cause principles in doing so; rather, it
endorsed them, *see id.* at 1633.

28

1 “corrective disclosure,” and instead discussed – as a form of proximate cause – the disclosure of the
2 “relevant truth,” *i.e.*, the revelation to the market of the true state of the company’s finances and
3 operations, previously hidden by fraud, thereby eliminating inflation in the price of the stock. *Dura*,
4 125 S. Ct. at 1631-32; *Plumbers & Pipefitters Local 572 Pension Fund v. Cisco Sys.*, 2005 U.S. Dist.
5 LEXIS 25398, at *19 (N.D. Cal. Oct. 26, 2005) (“The *Dura* decision only speaks in terms of the
6 ‘truth’ and ‘relevant truth.’”). In other words, the “relevant truth” may simply be the underlying
7 facts that were concealed – not how that was accomplished. *Dura*, 125 S. Ct. at 1631-32.

8 Courts applying *Dura*, including the Ninth Circuit and this Court, have held that there is no
9 requirement that a complaint allege a specific direct disclosure or admission that the prior statements
10 were false. *See, e.g., Daou*, 411 F.3d at 1026 (rejecting the district court’s insistence upon express
11 “negative public statements, announcements or disclosures,” the court held that it was sufficient to
12 allege that “disclosures of [the company’s] true financial health” led to a decline in stock price);
13 *Plumbers & Pipefitters*, 2005 U.S. Dist. LEXIS 25398, at *22 (“The FAC alleges that there was a
14 steep drop in the price of Cisco’s stock after Cisco Defendants began to disclose the alleged ‘truth’
15 about its financial condition.”); *Teamsters Local 445 Freight Div. Pension Fund v. Bombardier Inc.*,
16 2005 U.S. Dist. LEXIS 19506, at *58 n.155 (S.D.N.Y. Sept. 6, 2005) (“Although an allegation of a
17 corrective disclosure and resulting price decrease may be sufficient to plead loss causation in certain
18 cases, it is not necessary.”); *Parmalat*, 376 F. Supp. 2d at 510 (“[I]oss causation does not, as the
19 defendants would have it, require a corrective disclosure followed by a decline in price.”); *Whitehall*
20 *Jewellers*, 2005 U.S. Dist. LEXIS 12971, at *15-*17 (no requirement that the complaint allege a
21 specific direct disclosure or admission that prior financial statements were in fact false); *see also*
22 *Omnivision Tech.*, 2005 U.S. Dist. LEXIS 16009, at *18-*19 (*Dura* satisfied where complaint
23 simply alleged that “Plaintiffs purchased OmniVision securities at artificially inflated prices and
24 suffered damages when revelation of the true facts caused a decline in the value of their
25
26
27
28

1 investments’”).²²

2 Likewise, under ordinary proximate cause principles, the FAC’s theory of loss causation,
3 described and acknowledged in this Court’s October 11, 2005 Order, clearly demonstrates a causal
4 connection between Defendants’ fraud and the decline in Gilead’s stock price at the close of the
5 Class Period. The FAC alleges that Defendants were able to increase prescriptions and sales of
6 Viread by engaging in forbidden off-label marketing. Investors, unaware that these tactics had been
7 used to inflate Gilead’s performance, falsely attributed Viread’s explosive growth to legitimate
8 demand. However, in August, the FDA Warning Letter was made public, disclosing that the FDA
9 forbid Gilead from further engaging in illicit marketing. (¶199.) Although the market, in general,
10 did not recognize the significance of the letter immediately – because they were unaware of how
11 much Gilead depended on off-label marketing to increase demand for Viread, (¶¶192-94) – doctors
12 and competitors took the letter to heart, causing Viread prescriptions to drop off and, later, rebound
13 at a slower growth rate than in previous periods. (¶201.) The slowdown in demand led to a
14 predictable chain of events – wholesalers purchased less Viread from Gilead, and Gilead ultimately
15 reported disappointing results at the end of the Third Quarter. When the market received this news
16 Gilead’s stock price dropped. Because such a slowdown in sales, followed by a stock price decline,
17 was foreseeable and well within the “zone of risk” concealed by Defendants’ fraudulent conduct,
18 loss causation is properly alleged.

19 Though Defendants tacitly concede that loss causation exists if there has been stock price
20 drop following a disclosure of “true facts that had been the subject of the fraud” (Defs. Br. at 10),
21 Defendants argue that because the announcement of disappointing earnings for the Third Quarter did
22 not include a disclosure of illegal marketing or dependence on illegal marketing, such tactics could
23 not have “caused” the loss. Defendants fail to recognize that disclosure of the slowing growth was,
24 in every sense, a disclosure of the underlying facts concealed by the fraud – namely, the *true* demand

25 _____

26 ²² Requiring a “corrective disclosure” that establishes the falsity of prior statements as the only
27 means of establishing loss causation would enable wrongdoers to minimize or eliminate exposure
28 simply by refusing to admit, or otherwise delaying the disclosure of, fraudulent conduct.

1 for Viread, absent the illegal marketing tactics (or with such tactics inhibited). Thus, loss causation
2 is properly alleged. See *Omnivision*, 2005 U.S. Dist. LEXIS 16009, at *18-*19.

3 But more importantly, Defendants take too narrow a view of loss causation. Courts have
4 frequently found that a concealed adverse fact can cause additional problems – a snowballing of
5 debt, *Parmalat*, 375 F. Supp. 2d at 307, a drop in sales, *In re Allaire Corp. Sec. Litig.*, 224 F. Supp.
6 2d 319, 339 (D. Mass. 2002), a failed merger, *Semerenko v. Cendent Corp.*, 223 F.3d 165, 187 (3d
7 Cir. 2000), or a liquidity crisis, *Emergent Capital*, 343 F.3d at 198, that, ultimately, result in losses
8 to investors. All that is required to satisfy the element of proximate cause is that the losses are
9 foreseeable and thus flow in a “natural and probable consequence” from the fraudulent conduct.
10 This often occurs because of simple disclosure of the facts concealed by the fraud, but may also
11 happen when other consequences naturally flow from the fraud. Here, the October announcement of
12 disappointing revenues not only revealed the true demand for Viread, but *also* followed in a direct
13 chain from Defendants’ illegal marketing, and thus was a proximate result of the fraud.

14 Certainly, there is nothing surprising about the sequence of events described in the FAC.
15 Numerous courts have found that loss causation may be alleged by demonstrating a similar chain of
16 causation. In *Emergent Capital*, for example, approved by the Supreme Court in *Dura*, the Second
17 Circuit explained that loss causation existed when a company concealed an executive’s poor
18 business history, and, as it turned out, the executive’s incompetence ultimately caused his company’s
19 decline. 343 F.3d at 198-99. The Third Circuit in *Semerenko*, also approved in *Dura*, 125 S.Ct. at
20 1633, found loss causation could exist from a chain of events that, in the end, caused a corporation’s
21 board to reject a merger offer, resulting in a stock price drop. 223 F.3d at 187; *see also Schuster v.*
22 *Anderson*, 2005 U.S. Dist. LEXIS 35389, at *88-89 (N.D. Iowa Dec. 22, 2005) (“It is a reasonable
23 inference from the plaintiffs’ third amended complaint, that if Anderson and Cleveringa were using
24 Yournet’s capital to line their own pockets, the company would eventually find itself on the verge of
25 financial ruin.”); *Teamsters Local 445*, 2005 U.S. Dist. LEXIS 19506, at *57-58 (plaintiffs alleged a
26 “foreseeable chain of events” that began with poor underwriting, resulting in high risk loans,
27 resulting in high delinquency rates, resulting in repossession, resulting in declining earnings
28 expectations, resulting in write-offs, resulting in downgrading of the company’s certificates, and

1 finally resulting in the loss of plaintiff's investment); *Fraternity Fund Ltd. v. Beacon Hill Asset*
2 *Mgmt. LLC*, 376 F. Supp. 2d 385, 403 (S.D.N.Y. 2005) (loss causation exists where defendants'
3 failure to properly value securities in a fund ultimately resulted in the funds' collapse and the loss of
4 plaintiffs' investment). Nor can Defendants seriously argue that the losses were not entirely
5 foreseeable, for a slowdown in sales after a regulatory crackdown is an obvious "risk" of reliance on
6 illegal marketing tactics.²³ See *Parmalat*, 375 F. Supp. 2d at 307 (loss causation exists where
7 auditors concealed Parmalat's debt load; "[d]efendants reasonably could have foreseen that
8 Parmalat's inability to service its debt would lead to a financial collapse").

9 Indeed, this case is quite similar to *In re Allaire*.²⁴ In that action, plaintiffs alleged that the
10 defendants lied about the functionality of one of their products. Losses were incurred when
11 defendants were forced to report strikingly poor sales. See *id.* at 338. The court had no trouble
12 holding that these losses were sufficiently connected to the alleged fraud to satisfy the element of
13 loss causation: "As a truly practical matter, had any analyst been told that the product could not be
14 made to run absent time-consuming and costly customization, contrary to its advertised properties,
15 that analyst would have thought the information significant. Obviously, this would have impacted
16 sales, which in turn drive revenue and profits. To suggest otherwise is to insult the Court's
17 intelligence." *Id.* at 338-39. The court also rejected the argument that the actions of distributors and
18 customers broke the chain of causation sufficiently to constitute intervening causes. *Id.* at 338.

19 Similarly, it is not surprising that the market did not immediately react when the FDA letter
20 was disclosed in August. As Plaintiffs have alleged, the letter did not reveal the sheer *amount* of off-
21 label marketing – a necessary piece of the puzzle. (¶¶192-94.) It is not momentous that investors,
22 without access to internal data and unaware of what Second Quarter sales would look like, did not

23 _____
24 ²³ Of course, there may have been other risks involved, such as a risk of regulatory penalties.

25 ²⁴ Although *Allaire* pre-dated *Dura*, Judge Young used the appropriate loss causation standard. Not
26 only did he make clear that he rejected the Ninth Circuit's time-of-purchase standard, and instead
27 required a causal connection fraudulent conduct and plaintiffs' losses, 224 F. Supp. at 338, but in a
28 subsequent opinion, Judge Young defined loss causation to mean proximate cause and relied on his
earlier *Allaire* opinion. See *Crowell v. Ionics, Inc.*, 343 F. Supp. 2d 1, 22 & n.13 (D. Mass. 2004).

1 have enough information in August to draw the connection. And, in fact, there have been many
2 cases in which earnings statements or other financial disclosures demonstrating the impact of a
3 fraudulent practice served as the “disclosure” that caused the loss – even in situations where the
4 disappointing earnings did not immediately prove the falsity of prior statements. *See Allaire*, 224 F.
5 Supp. 2d at 339; *Montalvo v. Tripos, Inc.*, 2005 U.S. Dist. LEXIS 22752, at *26-27 (E.D. Mo. Sept.
6 30, 2005); *Parmalat*, 375 F. Supp. 2d at 307 (“That the true extent the fraud was not revealed to the
7 public until February - after Parmalat shares were worthless and after the close of the Class Period -
8 is immaterial where, as here, the risk allegedly concealed by defendants materialized during that
9 time and arguably caused the decline in shareholder and bondholder value.”).

10 Any proximate cause analysis must also determine whether an “intervening” cause – namely,
11 an “external and unforeseeable factor[,],” *Castellano*, 257 F.3d at 190– was responsible for the loss.
12 *See Dura*, 125 S.Ct. at 1632. For instance, if Gilead’s disappointing revenue figures were due to
13 some wholly unrelated issue – such as, say, a difficulty in manufacturing sufficient quantities of
14 Viread, or a general collapse of the industry – loss causation would not exist. *See Restatement*
15 §548A cmt b.²⁵

16 But whatever intervening causes Defendants may, at some point, contend were responsible
17 for the loss, it cannot be seriously argued based on the pleadings in this case that the disappointing
18 sales in the Third Quarter constituted an “intervening” cause, for those numbers flowed directly from
19 the FDA exposure of Defendants’ tactics. And the decisions of wholesalers to cut back their
20 purchases in light of reduced demand cannot be said to be an intervening cause, for it too is alleged
21 to flow directly from -- and was, in fact, caused by -- Defendants’ illegal conduct. *See Allaire*, 224
22 F. Supp. 2d at 338. Indeed, in any fraud involving retail sales, there will be entities such as
23 wholesalers and distributors who mediate between the end-users and the manufacturer, and where
24 they react to the market events caused by Defendants’ fraudulent conduct, they cannot be said to be
25 sufficiently independent to break the chain of causation. *Cf. Semerenko*, 223 F.3d at 186 (“to allow

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27 ²⁵ Of course, the existence, or not, of an intervening cause is ordinarily a matter for trial. *See*
28 *Emergent Capital*, 343 F.3d at 197.

1 any intervening change in market conditions not directly caused by the defendant to break the chain
2 of causation and exempt the defendant from liability would eviscerate Rule 10b-5” (citation
3 omitted)).

4 Therefore, because the FAC alleges that the injury to investors was a “natural and probable
5 consequence” of the fraud, and that the injuries were a foreseeable result of Defendants’ wrongful
6 conduct, loss causation is alleged.

7 2. The FAC Meets the Pleading Standards of *Dura*

8 Defendants’ alternative argument is that, as a *factual* matter, the FAC fails to properly allege
9 that losses occurred in the manner described. They dispute that there was any slowdown in Viread
10 growth, and that such a slowdown cannot be inferred from wholesalers’ decisions to draw down
11 inventory. (Defs. Br. 13-14.) Defendants’ arguments are simply inappropriate at this stage of
12 litigation. *See Lee v. City of L.A.*, 250 F.3d 668, 688 (9th Cir. 2001); *Am. West*, 320 F.3d at 936;
13 *Adams v. Kinder-Morgan*, 340 F.3d 1083, 1101 (10th Cir. 2003). Indeed, Defendants have turned
14 the Court’s review of the sufficiency of Plaintiffs’ pleading into a *de facto* examination of the merits
15 of Plaintiffs’ claims. The Court should recognize the sufficiency of the FAC’s allegations and
16 should decline Defendants’ tacit invitation to require Plaintiffs to *prove* their case at the motion to
17 dismiss stage.

18 A complaint need only provide “some indication” of the causal connection between the
19 losses and the fraud. *Daou*, 411 F.3d at 1026. Here, Defendants repeat back the precise loss
20 causation allegations in order to refute them. (Defs. Br. at 2.) There thus can simply be no dispute
21 that they do, in fact, have “some indication” – and, indeed, a complete understanding – of the causal
22 connection alleged. For that reason alone, the FAC adequately alleges loss causation.

23 Moreover, even if Defendants’ factual challenges to the FAC are to be entertained, it is clear
24 that Plaintiffs’ allegations are at least sufficient to survive a motion to dismiss. Plaintiffs have
25 demonstrated that the market was concerned about a slowing of Viread demand and the degree to
26 which wholesalers chose to draw down existing inventories. (¶¶206-07.) This was more than
27 “normal” drawdown to previous inventories – this was the lowest level of inventory – *for a drug*
28

1 *with a growing demand* – that had been seen in four quarters, a fact which analysts found significant.
2 (¶204.) Plaintiffs have also cited a chart, which Defendants submitted to the Court, that indisputably
3 shows not only that sales dropped in August, but that the growth rate was slowing compared to prior
4 periods. (Defs. Exh. G.) Indeed, Defendants themselves point out that Viread sales tended to exhibit
5 a peak-and-valley pattern, (Defs. Br. at 13), but following the August release of the FDA letter, the
6 next “peak” was noticeably lower than it had been in prior periods. The chart also shows that new
7 prescriptions exhibited lower growth than they had shown in prior quarters. And it is certainly a
8 reasonable inference that this relatively poor performance affected wholesaler purchasers.²⁶

9 Defendants point out that Bear Stearns described “strong growth” in prescriptions on October
10 8, and estimated end-user demand at the same rate in the Third Quarter as it had existed in the
11 Second Quarter. (Defs. Br. 13-14.) But the report also repeatedly states that end-user demand was
12 below its estimates, and that it was lowering targets for the Fourth Quarter as a result, as the FAC
13 points out. (¶206; Defs. Exh. I, p.2.) Defendants also argue that there are other reasons why
14 wholesalers may have behaved as they did – and speculate that the drawdown was “normal” and
15 expected in light of the overstocking, (Defs. Br. at 14) -- but these alternative explanations cannot
16 possibly be accepted as true on motion to dismiss, particularly where, as here, Plaintiffs have shown
17 that market analysts, presumably experts on such matters, *found the drawdown to be surprising*
18 *despite their knowledge of the wholesaler stocking in the previous quarter.* At bare minimum, these

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22 ²⁶ Nor can any negative inferences or conclusions be drawn from the fact that Gilead reported
23 increased sales of Viread in later quarters. (Defs. Br. at 15.) In late 2003, the FDA approved Viread
24 for use in treatment naïve HIV patients. (¶152.) For the first time, Gilead was could legally market
25 to and capture this market segment. But the post hoc approval of Viread for broader indications does
26 not mitigate the losses to investors prior to October. Those investors believed Viread, which had
27 only been approved for narrow indications, sales would go up *even further* if broader indications
28 were approved. *See Goldberg v. Household Bank*, 890 F.2d 965, 966 (7th Cir. 1989) (“a firm that
lies about some assets cannot defeat liability by showing that other parts of its business did better
than expected, counterbalancing the loss.”); *Pommer v. Medtest Corp.*, 961 F.2d 620, 623 (7th Cir.
1992) (“securities laws approach matters from an *ex ante* perspective: just as a statement true when
made does not become fraudulent because things unexpectedly go wrong, so a statement materially
false when made does not become acceptable because it happens to come true.”).

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1 kinds of factual disputes simply cannot be resolved at the pleading stage.²⁷

2 **D. Plaintiffs Adequately Allege Defendants' Misrepresentations**
 3 **Regarding the Off-Label Marketing of Viread**

4 **1. Plaintiffs Sufficiently Allege That Defendants Engaged in Off-**
 5 **Label Marketing**

6 In a half-hearted attempt to convince the Court to reconsider its prior determination regarding
 7 the sufficiency of Plaintiffs' allegations, Defendants once again take the position that the specific,
 8 illegal marketing identified in the FAC was fully consistent with Viread's label and thus was
 9 completely proper as a matter of law. (Defs. Br. at 16-17.)²⁸ Defendants misinterpret Viread's
 10 Package Labeling to assert that any HIV patient could use Viread and contend that the FAC fails to
 11 connect the off-label marketing scheme to second quarter 2003 reports. (Defs. Br. at 16-20.)²⁹

12 Rather than repeating the details from previous memoranda, and thus illegal, Plaintiffs
 13 respectfully refer the Court to pages 11-18 of Plaintiffs' Memorandum of Points and Authorities In
 14 Opposition to Defendants' Motion to Dismiss the TAC dated July 11, 2005 (the "Opposition
 15 Brief").³⁰ In those pages, Plaintiffs: (i) detail what constitutes off-label marketing (pg. 12-14); (ii)
 16 describe that the FDA did not approve Viread for use in treatment naïve patients until late 2003 (pg.
 17 15-16); (iii) demonstrate that the FDA never approved Viread as a treatment for HBV (pg. 16-17);
 18 (iv) describe how Defendants minimized key safety information for Viread in their illegal marketing

19 ²⁷ Plaintiffs cannot be expected to provide further details of the precise degree to which disclosure of
 20 the FDA Warning Letter impacted Gilead sales and prescriptions. Not only are loss causation
 21 allegations only subject to notice pleading, as described above, but as Plaintiffs alleged in the FAC,
 22 such information is exclusively in the hands of Defendants and third parties. (¶201.) *Cf. Shapiro v.*
UJB Fin. Corp., 964 F.2d 272, 285 (3d Cir. 1992) (Rule 9(b) requirements will be relaxed for
 information exclusively in defendants' control so long as plaintiffs specify the information they
 require and explain that it is not publicly available).

23 ²⁸ Defendants rehash old arguments that do not warrant reconsideration. *See* N.D. Cal. L.R. 7-9.

24 ²⁹ In addition to ignoring the prior ruling of the Court that off-label marketing occurred and
 25 Defendants were aware of it, Defendants not only ignore the law of the case but improperly attempt
 to inject disputed factual issues not cognizable at the pleading stage. *See Lee*, 250 F.3d at 688-90;
Am. West, 320 F.3d at 935-36; *Adams*, 340 F.3d at 1101.

26 ³⁰ Similarly, as Defendants' safe harbor assertions have not changed, and in the interests of
 27 economy, Plaintiffs respectfully refer the Court to pages 21 through 22 of their Opposition Brief
 concerning the TAC for Plaintiffs' safe-harbor and bespeaks caution arguments.

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1 scheme (pg. 17-18); and (v) clearly show how allegations that 75%-95% of all Viread sales resulted
 2 from off-label marketing are reasonable by referring the Court to the rampant, systematic off-label
 3 promotion of Neurontin by Warner-Lambert Company (pg. 18).³¹

4 **2. Plaintiffs Adequately Allege Defendants' Misrepresentations**
 5 **Regarding Wholesaler Overstocking As Those Allegations**
 6 **Relate to the Sales of and Demand for Viread**

7 In June 2003, in order to further exploit the artificial demand that Defendants created for
 8 Viread, Gilead announced a price increase for Viread further enticing drug wholesalers to stock up
 9 on Viread before the increase went into effect. As set forth in the FAC and above, between 75% and
 10 95% of Gilead's sales of Viread during the Class Period were caused by off-label marketing.
 11 Because the market was not told that off-label marketing was the cornerstone of Viread demand, this
 12 mistaken impression led to wholesaler overstocking. (¶¶9, 171, 198.) When the wholesaler
 13 overstocking materially increased and subsequently decreased Gilead's sales of Viread during the
 14 Class Period, off-label sales of Viread were enormous.

15 This Court already determined that Plaintiffs sufficiently alleged Defendants were aware of
 16 the illegal Viread off-label marketing scheme. Because of this awareness, and because a huge
 17 percentage of Viread's domestic sales figures were the result of off-label marketing, Defendants also
 18 knew wholesalers would overstock Viread in reliance on inflated sales figures and the expectation of
 19 being able to move large quantities of the drug to doctors, pharmacies, and patients. (See ¶¶166-73.)
 20 Without the off-label marketing, wholesalers, who operate on a razor thin profit margin, would have

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 22 ³¹ Defendants once again assert, without specification, that FAC allegations attributed to Plaintiffs'
 23 Confidential Witnesses are in "direct conflict" with similar allegations in the Consolidated Amended
 24 Complaint, claiming the result is a sham pleading that should be stricken. (Defs. Br. at 18.)
 25 Defendants are wrong. In the interest of economy, Plaintiffs respectfully refer the Court to page 19
 26 of the Opposition Brief for an explanation of how CW1 and CW2 merely clarified in the TAC and
 27 FAC, not contradicted, their accounts of off-label marketing while at Gilead. The clarification
 28 between the Consolidated Amended Complaint and FAC exists because of additional, specific facts
 – not because of contradictory sham allegations. Considering that "[a]ll allegations of material fact
 made in the complaint are taken as true and construed in the light most favorable to the plaintiff," the
 Court reject Defendants' motion to strike. *See Am. West*, 320 F.3d at 931. Defendants will have
 every opportunity to examine CW2's recollections in discovery.

1 known the true demand for Viread and would not have stockpiled it. (¶¶168, 171, 198.)³²

2 **E. Plaintiffs Adequately Plead Defendants’ Control Person Liability**

3 The FAC adequately alleges Gilead committed a primary violation of §10(b) and Rule 10b-5
4 and that the Individual Defendants, who held active, executive positions within the Company,
5 controlled the primary violator. (See ¶¶25-32). *Adams*, 340 F.3d at 1108; *In re Adaptive Broadband*
6 *Sec. Litig.*, 2002 U.S. Dist. LEXIS 5887 at *58-59 (N.D. Cal. Apr. 2, 2002) (“fact that the named
7 individual defendants held important positions in the company is sufficient at the pleadings stage”).
8 Thus, Plaintiffs have adequately alleged a *prima facie* case under §20(a) of the Exchange Act.³³

9 **F. Leave to Amend**

10 If this Court determines that the FAC does not meet PSLRA pleading requirements, Plaintiffs
11 should be given leave to amend pursuant to Federal Rule of Civil Procedure 15(a). *Eminence*
12 *Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003).

13 DATED: January 20, 2006

14 By:

15 /s/

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22 ³² The wholesaler overstocking should be considered as part of the totality of Plaintiffs’ scienter
23 allegations. Plaintiffs recognize the Court previously held that insider stock sales, alone, are
24 insufficient to adequately plead scienter. The Court relied on *Ronconi v. Larkin*, 253 F.3d 423 (9th
25 Cir. 2001) and *In re Silicon Graphics, Inc. Sec. Litig.*, 183 F.3d 970 (9th Cir. 1999). Each of these
26 cases is distinguishable because there were no other facts remaining in these cases to support
27 scienter. See *Silicon Graphics*, 183 F.3d at 985; *Ronconi*, 253 F.3d at 434. Here, Plaintiffs alleged
28 sufficient facts to raise a strong inference that Defendants had knowledge of the Company’s off-label
marketing. (See Order at 9.) The stock sales further bolster Plaintiffs’ scienter allegations.

³³ The determination of whether a person is a control person “is an intensely factual question.” *Id.*;
see also In re Cylink, 178 F. Supp. 2d. 1077 (N.D. Cal. 2001).

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PROOF OF SERVICE

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

On January 20, 2006, I served the following document(s):

**PLAINTIFFS' CORRECTED MEMORANDUM OF POINTS
AND AUTHORITIES IN OPPOSITION TO DEFENDANTS'
MOTION TO DISMISS THE FOURTH CONSOLIDATED
AMENDED COMPLAINT**

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11 service offices for next-day delivery the same day as the correspondence is placed for collection.

12 Executed January 20, 2006, at San Francisco, California.

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