

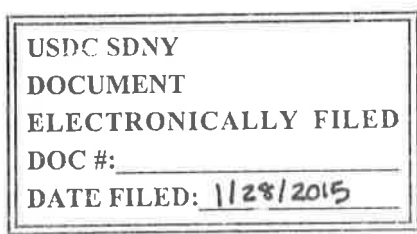
UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE SANOFI SECURITIES LITIGATION :  
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13 Civ. 8806 (PAE)  
14 Civ. 2211 (PAE)

OPINION & ORDER

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AG FUNDS, L.P., et al., :  
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Plaintiffs, :  
:  
-v- :  
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SANOFI, GENZYME, CHRISTOPHER VIEHBACHER, :  
DAVID MEEKER, and JEROME CONTAMINE, :  
:  
Defendants, :  
:  
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PAUL A. ENGELMAYER, District Judge:

In these related cases brought under the securities laws, plaintiffs claim that the pharmaceutical company Sanofi, its predecessor Genzyme, and three company executives (collectively, “defendants,” “Sanofi,” or “the company”) made false and misleading statements about Lemtrada, a multiple sclerosis (“MS”) drug, while it was under review by the U.S. Food and Drug Administration (“FDA”). Although plaintiffs find multiple faults with Sanofi’s public pronouncements, their core allegation is that defendants failed to disclose concerns the FDA had expressed about the “single-blind” design used in Lemtrada’s clinical trials, and that this omission made Sanofi’s public statements about Lemtrada false and misleading.

Plaintiffs allege violations of §§ 10(b), 18, and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78a *et seq.* (the “Exchange Act”); §§ 11 and 12 of the Securities Act of 1933,

15 U.S.C. § 77a *et seq.* (the “Securities Act”); and state blue sky laws. Pending now are defendants’ motions to dismiss both complaints for failure to state a claim, under Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, the Court grants these motions in full and dismisses both complaints.

## **I. Background<sup>1</sup>**

Sanofi, based in Paris, is the fifth largest pharmaceutical group in the world. CAC ¶¶ 2, 39; AGC ¶¶ 14, 21. In 2011, Sanofi acquired Genzyme, a pharmaceutical company based in Cambridge, Massachusetts. CAC ¶ 8; AGC ¶¶ 15, 25. At the time, Genzyme was in the process of developing and testing a MS drug called alemtuzumab, commonly known as “Lemtrada.” CAC ¶ 6; AGC ¶ 22.

Largely because Sanofi and Genzyme could not agree on a valuation of Lemtrada, Sanofi issued contingent value rights (“CVRs”) to all Genzyme shareholders as part of the acquisition. CAC ¶ 9; AGC ¶ 24. The CVRs were tradable on the open market. CAC ¶ 39; AGC ¶ 3. They

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<sup>1</sup> These facts are drawn primarily from the Consolidated Amended Complaint, 13 Civ. 8806, Dkt. 44 (“CAC”), and the AG Funds et al. Complaint, 14 Civ. 2211, Dkt. 2 (“AGC”). For the purpose of resolving the motion to dismiss, the Court assumes all well-pled facts to be true and draws all reasonable inferences in favor of plaintiffs. *See Koch v. Christie’s Int’l PLC*, 699 F.3d 141, 145 (2d Cir. 2012). The Court also considered the documents attached to the Declaration of Joshua S. Amsel in support of the motion to dismiss. 13 Civ. 8806, Dkt. 50; 14 Civ. 2211, Dkt. 19 (“Def. Decl.”). Because these documents were incorporated into the CAC and AGC by reference, or are matters of public record, they are properly considered on a motion to dismiss. *See City of Pontiac Policemen’s & Firemen’s Ret. Sys. v. UBS AG*, 752 F.3d 173, 179 (2d Cir. 2014) (In resolving a motion to dismiss, the court “may consider,” *inter alia*, “any statements or documents incorporated in it by reference, as well as public disclosure documents required by law to be, and that have been, filed with the SEC, and documents that the plaintiffs either possessed or knew about and upon which they relied in bringing the suit.”) (citation omitted). The Court considered these documents “not for the truth of the matters asserted therein,” but only “for the fact that the statements were made.” *Clark v. Kitt*, No. 12 Civ. 8061 (CS), 2014 WL 4054284, at \*7 (S.D.N.Y. Aug. 15, 2014); *see also, e.g., Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008) (“[I]t is proper to take judicial notice of the *fact* that press coverage, prior lawsuits, or regulatory filings contained certain information, without regard to the truth of their contents.”).

entitled holders to cash payments upon the achievement of certain milestones. One important milestone was obtaining FDA approval for Lemtrada by March 31, 2014. CAC ¶ 10; AGC ¶ 26.

After completing the Genzyme acquisition, Sanofi continued to move Lemtrada forward in the clinical testing and FDA approval process. *See* CAC ¶¶ 12, 15; AGC ¶ 52.

On November 8, 2013, the FDA Advisory Committee on Peripheral and Central Nervous System Drugs (“Advisory Committee”) issued a briefing report that “sharply criticized” Sanofi’s application for FDA approval of Lemtrada. CAC ¶ 19; *see also* AGC ¶ 55. Based on the Report, it was apparent that the FDA would not approve Sanofi’s application. *See id.* That day, the price of the CVRs declined from \$2.00 to \$0.77 per share. CAC ¶ 22; AGC ¶ 57. Soon after, the FDA formally rejected Sanofi’s application. CAC ¶ 25; AGC ¶ 58. The price of the CVRs thereafter declined to \$0.32 per share. CAC ¶ 26; AGC ¶ 58. On November 14, 2014, however, well after the filing of these lawsuits, the FDA reversed its initial decision and approved Lemtrada for use by certain MS patients. *See* 13 Civ. 8806, Dkt. 55.

Plaintiffs are individuals and corporations that purchased CVRs before November 8, 2013.<sup>2</sup> CAC ¶ 1; AGC ¶ 5. They allege that, before the release of the November 8, 2013 FDA Report that triggered a sharp drop in the CVRs’ price, defendants made misleading and incomplete statements about the likelihood of obtaining timely FDA approval for Lemtrada, the drug’s safety and efficacy, and the results of the ongoing clinical trials. *See* CAC ¶ 13; AGC ¶ 2. Most centrally, plaintiffs claim that the FDA had conveyed to Genzyme executives that the single-blind design of Lemtrada’s clinical trials could bias the study, such that the trial results

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<sup>2</sup> As pled in the CAC, the class period runs from March 6, 2012 to November 7, 2013; the class is comprised of purchasers of CVRs during that period. CAC ¶ 1. As for the AGC, it alleges that its plaintiffs, who were excluded from or opted out of the class, purchased CVRs before November 8, 2013, AGC ¶¶ 7–12, or received CVRs directly from Sanofi in exchange for shares of Genzyme during Sanofi’s acquisition of Genzyme in 2011, AGC ¶ 13.

would have to be particularly robust to overcome that design impediment, *see, e.g.*, CAC ¶ 23; AGC ¶ 36, and that Genzyme’s and later Sanofi’s failure to disclose that interim feedback made its encouraging statements about the drug’s prospects misleading, *see* CAC ¶ 21; AGC ¶ 37.

Plaintiffs allege that they relied on defendants’ statements in deciding to acquire CVRs. CAC ¶¶ 92–97, 106; AGC ¶¶ 53–54. Based on these factual allegations, plaintiffs assert various violations of federal and state securities laws. CAC ¶¶ 100–15; AGC ¶¶ 61–106.

## **A. Factual Background<sup>3</sup>**

### **1. Genzyme Develops Lemtrada**

MS is “a potentially debilitating autoimmune disease that affects the brain and central nervous system of an estimated 400,000 people in the United States and 2.5 million worldwide.” CAC ¶ 78 (quoting a *Boston Globe* article). In the early 2000s, a non-party company, ILEX, began developing Lemtrada as a drug to combat MS. *See* AGC ¶ 36(a). In 2002, clinical trials of Lemtrada began. *See* CAC ¶ 30; AGC ¶ 36(a). In 2004, while Lemtrada was in the second of three phases of clinical trials, Genzyme acquired ILEX. *See* AGC ¶ 36(a). Genzyme continued the Lemtrada studies and released safety and efficacy updates on an annual basis. *See* Def. Decl. Exs. 14 (2005), 15 (2006), 16 (2007), 18 (2010).

One of Lemtrada’s primary benefits is its unique treatment regimen: While many MS drugs must be taken daily or weekly, Lemtrada is administered intravenously during two annual courses of treatment. CAC ¶ 7. In part for this reason, in 2010, Lemtrada had an estimated value of \$14 billion worldwide. *Id.* ¶ 6. However, Lemtrada’s distinctive method of administration made it difficult or impossible to conduct “double-blind” studies—ones in which the nature of

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<sup>3</sup> Defendants’ declarations in support of each motion are substantially similar although not identical. As used here, the citations to “Def. Decl.” refer to the documents filed in the class-action case, 13 Civ. 8806, at docket number 50.

the treatment being administered is concealed from both subjects and investigators. *See* Def. Decl. Ex. 9, at 4 (“FDA Guidance for Industry”).<sup>4</sup> The Lemtrada studies therefore had a single-blind design: The investigators were not aware of each subject’s assigned treatment, but the subjects knew whether they were receiving Lemtrada or a competitor drug commonly known as Rebif. The fact that the single-blind design was being used was reported in various publicly available sources. *See* Def. Decl. Exs. 12, 13, 17, 22, 28–29.

As early as 2002, the year the Lemtrada clinical trials began, the FDA expressed concerns about the single-blind design of the study. CAC ¶ 23; AGC ¶ 36. In that year, the FDA advised ILEX and Genzyme that the Lemtrada clinical trials “will not provide substantial support” for a license application. AGC ¶ 36(a); *see also id.* ¶¶ 36(b)–(c). Defendants did not publicly disclose this interim feedback. *See, e.g.*, CAC ¶ 13; AGC ¶ 35.

In 2005, a patient who had received Lemtrada died of sepsis, and the FDA placed the clinical trial on hold for approximately 10 months. CAC ¶ 31; AGC ¶ 36(d). Genzyme disclosed information about the hold in a press release. Def. Decl. Ex. 14, at 3, 4. A confidential witness (“CW”) employed by Genzyme between 2002 and 2012 reported that, even when the FDA lifted the hold, Genzyme employees remained concerned about Lemtrada’s safety profile. CAC ¶¶ 29–32. Additionally, a Steering Committee composed of high-level Genzyme executives was “hypersensitive” to concerns about Lemtrada’s safety and the potential impact of the reported adverse events on Lemtrada’s commercial viability. *Id.* ¶ 32.

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<sup>4</sup> “Double blind” means that “both subjects and investigators . . . are unaware of each subject’s assigned treatment.” FDA Guidance for Industry at 4. Clinical trials of new pharmaceuticals “usually include randomization and blinding of patients or investigators, or both.” 21 C.F.R. § 314.126(b)(2)(i). The FDA prefers double-blind studies because “[b]linding is intended to minimize the potential biases resulting from differences in management, treatment, or assessment of patients, or interpretation of results that could arise as a result of subject or investigator knowledge of the assigned treatment.” FDA Guidance for Industry at 4.

By 2006, however, the FDA's position had shifted. On November 21, 2006, for example, Genzyme met with the FDA and included the following in the minutes of the meeting:

FDA responded that a rater blinded (but patient not blinded) study may be adequate if the effect is large. However, a totally blinded study is more likely to be found persuasive if the treatment effect is relatively small. . . . The FDA again noted that they prefer double-blinded, controlled studies, especially for the pivotal trials.

CAC ¶ 23(a). In other words, the FDA determined that it would accept data from the clinical trials, but the treatment effect would have to be "large" to win FDA approval.

Similarly, a June 29, 2007 letter from the FDA reiterated the agency's position regarding the study design:

FDA strongly recommends that you use a double-dummy placebo control in your pivotal trials. The acceptability of your rater-blinded study will be a matter of review. If your study results reveal an extremely large effect, then FDA may potentially accept this rater-blinded design for the pivotal trials.

*Id.* ¶ 23(b); AGC ¶ 36(e). The FDA permitted Lemtrada to enter Phase III clinical trials in September 2007 with a single-blind design. *See* CAC ¶ 12; AGC ¶¶ 43, 44, 46; *see also* Def. Decl. Ex. 20, at 2.

On October 23, 2008, physicians involved in the Lemtrada studies published full results of the Phase II clinical trial in *The New England Journal of Medicine*. Def. Decl. Ex 17. This publication described the single-blind design of the study and disclosed every adverse event that had been observed to date. *Id.* It did not, however, disclose the FDA's stated concerns about the single-blind design of the Lemtrada studies. CAC ¶ 27; AGC ¶¶ 35, 37.

The FDA continued to express concerns about the design of the Lemtrada studies during the Phase III trials. Minutes from a March 17, 2010 meeting with Genzyme officials reflect that the FDA was:

concerned by the potential bias introduced by the absence of blinding of patients, the possibility of unblinding of EDSS raters, the initiation of alternative MS therapies after the first relapse, and the elimination of censoring. The interpretation of the results from the statistical analysis will be challenging, and extremely robust findings will be necessary to overcome these issues. . . . Blinding procedures were discussed in detail. For EDSS and relapse reporting, the bias introduced by unblinding of physicians and patients remains a significant problem which will cause serious difficulties in interpreting the results of the trial.

CAC ¶ 23(c); AGC ¶ 36(f).

Notwithstanding these issues, Sanofi reported that the FDA had placed the Phase III Lemtrada studies on a fast track. AGC ¶ 42; Def. Decl. Ex. 32, at 12. The fast-track procedure is “designed to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening and severely-debilitating illnesses.” 21 C.F.R. § 312.80.

On January 24, 2011, the FDA again noted its concerns about the single-blind design of the Lemtrada study, during a meeting with Genzyme officials:

The lack of blinding remains a major concern. We note that, despite these previous concerns that have been communicated to you, there was little discussion of the unblinded design of the trials in the meeting material. We emphasize the importance of presenting a full discussion and analysis of the impact of having the patients and treating physicians unblinded.

CAC ¶ 23(d); AGC ¶ 36(g).

## **2. Sanofi Acquires Genzyme and Issues the CVRs**

In mid-2010, Sanofi initiated efforts to acquire Genzyme. CAC ¶ 8; AGC ¶ 22. The two companies negotiated for several months and reached a final agreement on February 16, 2011. CAC ¶ 8; AGC ¶¶ 24–25. Under their agreement, Sanofi acquired Genzyme for more than \$20 billion. CAC ¶ 8. However, largely because Sanofi and Genzyme could not agree on an exact valuation of Lemtrada, Sanofi also consented to issue one CVR for each share of Genzyme. *Id.* ¶ 9; AGC ¶¶ 24, 26. In total, Sanofi issued more than 200 million CVRs. *See* AGC ¶ 5.

The CVRs, which were tradable on the open market, derived their value from cash payments Sanofi would make if the company achieved certain milestones. CAC ¶ 10; AGC ¶ 26. One milestone entitled CVR holders to \$1 per CVR if Lemtrada received FDA approval by March 31, 2014. Four other milestones entitled CVR holders to as much as \$13 per CVR if Lemtrada reached certain sales targets. *Id.* Although Sanofi is a global company, regulatory approval within the United States (*i.e.*, by the FDA) “was a critical first step” to achieving the sales milestones because the U.S. “accounts for 20% of MS patients worldwide.” CAC ¶ 11. A final milestone entitled CVR holders to payments of \$1 per share if two other Genzyme drugs met production milestones. AGC ¶ 28. If all six milestones had been reached, Sanofi would have paid an additional \$3.8 billion in connection with the acquisition of Genzyme. CAC ¶ 9.

On March 7, 2011, Genzyme filed a Schedule 14D-9 with the SEC. Def. Decl. Ex. 31 (“Genzyme 14D-9”). The 14D-9 was used to persuade Genzyme shareholders to accept Sanofi’s offer. AGC ¶ 29. In it, Genzyme projected a 90% likelihood that Lemtrada would be approved by March 31, 2014, fulfilling the first payment-triggering milestone. *Id.* ¶¶ 30, 40; Genzyme 14D-9, at 45. Genzyme also stated in the 14D-9, as on other occasions, that it “anticipates product approval in the United States in the second half of 2012.” AGC ¶¶ 40, 42, 43, 44. As to the Lemtrada sales milestones, Genzyme projected an 80% likelihood of reaching the first, a 54% likelihood of reaching the second, a 50% likelihood of reaching the third, and a 16% likelihood of reaching the fourth. *Id.* ¶ 30; Genzyme 14D-9, at 45. These “projections were accompanied with boilerplate caveats” but did not reveal the negative feedback Genzyme had received from the FDA regarding the single-blind study design. AGC ¶¶ 31, 34, 43, 44.

With the approval of Genzyme shareholders, Sanofi completed the acquisition of Genzyme on April 8, 2011. *See id.* ¶ 33.



### 3. Sanofi Continues Testing Lemtrada

After acquiring Genzyme, Sanofi continued the Lemtrada clinical trials and made numerous statements about the drug in press releases, earnings conference calls with analysts, and SEC filings. *See* CAC ¶¶ 45–73; AGC ¶¶ 45–52. Like its predecessor Genzyme, Sanofi released annual updates about Lemtrada. Def. Decl. Exs. 24–26 (2011), 27 (2012), 30 (2013). It also disclosed complete Phase III trial results, including all reported adverse effects, in two research articles published in *The Lancet* in November 2012. Def. Decl. Exs. 28–29.

The Form 20-F Sanofi submitted on March 6, 2012 is representative of the statements defendants made in SEC filings between 2011 and 2013. It reported, *inter alia*, that “two Phase III studies demonstrating the safety and efficacy of [Lemtrada] were completed in 2011.” CAC ¶ 45; AGC ¶ 47. Those studies “demonstrated strong and robust treatment effect” and a “significantly reduced” relapse rate as compared to Rebif, the leading competitor. Additionally, the Form 20-F stated, the “safety results were consistent with previous [Lemtrada] use in MS, and adverse events continued to be manageable.” *Id.*

During a conference call with analysts on April 27, 2012, Sanofi’s CEO, Christopher Viehbacher, characterized the results of the Phase III studies as “nothing short of stunning.” CAC ¶ 49. In describing safety concerns associated with Lemtrada, Viehbacher stated: “People are concerned about safety, but I don’t see the reason for that. We’ve seen higher incidence on impact for thyroid, but thyroid conditions are not uncommon in this population and indeed others and are pretty easily treated with standard therapy. The ITP [an immune disorder] has not been as severe as we’ve seen outside there the population and is [sic] all been reversed.” *Id.* ¶ 50.

On June 12, 2012, Sanofi issued a press release announcing its submission of a supplemental Biologics License Application (“sBLA”) to the FDA. *Id.* ¶¶ 15, 52; AGC ¶ 49.

Under the Public Health Service Act, firms must obtain licenses before marketing and selling pharmaceuticals in interstate commerce. 42 U.S.C. § 262(a). The sBLA provided specific information about Lemtrada to allow the FDA to determine whether to issue a license. *See* 21 C.F.R. § 601.20(d). The press release quoted Genzyme’s President and CEO, David Meeker, as stating that Lemtrada “has the potential to transform the lives of patients with Multiple Sclerosis.” CAC ¶ 52. On July 26, 2012, Sanofi CEO Viehbacher similarly told analysts that Lemtrada “is a potential game changer.” *Id.* ¶ 54.

On August 27, 2012, Sanofi announced that it had received a “Refuse to File” letter from the FDA. *Id.* ¶ 16. “The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review.” 21 C.F.R. § 314.101(a). The FDA may refuse to file an application in a number of circumstances, including because “[t]he application does not contain a completed application form” or “does not on its face contain information required under” applicable law. *Id.* § 314.101(d). Sanofi’s announcement reported that the FDA had merely asked Sanofi to modify its presentation of the data “to enable the agency to better navigate the application.” CAC ¶ 16.

After receiving the “Refuse to File” letter, Sanofi continued to make optimistic statements about Lemtrada’s prospects. During a conference call on October 25, 2012, for example, Sanofi’s CFO, Jerome Contamine, told analysts that the financial results “will continue and probably somewhat amplify in the coming quarters as we prepare for the launch of Lyxumia, thereafter for the launch of Lemtrada.” *Id.* ¶ 56. During the same call, Viehbacher said that he was “actually very satisfied with where the progress is going.” *Id.* ¶ 57. Plaintiffs understood these statements to suggest that the Lemtrada launch was imminent. *Id.*

On January 28, 2013, Sanofi announced that the FDA had accepted its sBLA seeking approval for Lemtrada. *Id.* ¶¶ 18, 61; AGC ¶ 50. Sanofi stated that it expected the FDA to make a final decision as to Lemtrada during the second half of 2013. CAC ¶ 18.

Soon after, on February 7, 2013, Viehbacher told analysts that Sanofi “should be in a good position to launch Lemtrada. It is obviously a huge opportunity that we have to be able to put two significant new medicines”—Lemtrada and another Sanofi drug, Aubagio—“into an important area like MS. This is a market of some \$14 billion worldwide.” *Id.* ¶ 63. Sanofi executives made similarly optimistic statements over the next several months. On October 30, 2013, for example, Viehbacher told analysts “quite honestly, I’m feeling pretty relaxed because if I look at our Phase III pipeline, there’s an awful lot of really good stuff in there . . . . We’ve got Aubagio and Lemtrada rolling out.” *Id.* ¶ 73.

By early 2014, Lemtrada had been approved for marketing and distribution in the European Union, Canada, Australia, Mexico, and Brazil, a total of more than 30 countries. Def. Decl. Exs. 45, 48–51.<sup>5</sup>

#### **4. The FDA Denies Approval of Lemtrada**

On November 8, 2013, the FDA Advisory Committee issued a report on Lemtrada. CAC ¶¶ 19, 75; AGC ¶ 55. The FDA Report “sharply criticized” Sanofi’s submissions and stated that

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<sup>5</sup> These approvals are readily discovered by searching the websites of foreign regulatory agencies and other neutral, third-party sources. For example, the European Commission’s Register of Pharmaceuticals includes the decision approving Lemtrada on September 16, 2013. *See* <http://ec.europa.eu/health/documents/community-register/html/h869.htm>. And a nonprofit organization named MS-UK has aggregated news stories reporting on Lemtrada approval in all of these countries. *See* <http://www.ms-uk.org/lemtrada>. Because approval of Lemtrada in these countries is an adjudicative fact that “is not subject to reasonable dispute” and “can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned,” the Court may properly take judicial notice of it. Fed. R. Evid. 201; *see also, e.g., Garb v. Republic of Poland*, 440 F.3d 579, 594 & n.18 (2d Cir. 2006). If the Court had refused to consider this fact, however, it would have reached the same conclusions regarding whether defendants’ statements were actionable. *See* pgs. 36–37, 49, 54, *infra*.

“significant concerns exist regarding the safety profile of [Lemtrada] and the adequacy of the efficacy data.” CAC ¶¶ 19, 75; *see also* AGC ¶ 56. All three doctors involved in the FDA Report recommended against approving Lemtrada. Dr. Evelyn Mentari, who examined the safety of Lemtrada, found “serious and potentially fatal” safety concerns including autoimmune diseases and thyroid disorders; she therefore recommended against approval “unless substantial clinical benefit exists.” CAC ¶¶ 76; AGC ¶ 56. Dr. John Marler, who assessed the efficacy of Lemtrada, expressed “grave concerns” regarding “the failure to blind patients and treating physicians”; he therefore concluded that Sanofi “ha[d] not submitted evidence from adequate and well-controlled studies to support the effectiveness of [Lemtrada].” *Id.* Dr. Sharon Yan, who reviewed the statistical analysis presented by Sanofi, likewise found “that troublesome design issues and the presence of bias in the trials prevents reliance on their results.” *Id.*

Following the release of the FDA Report, the market price of the CVRs declined nearly 62%, from \$2.00 to \$0.77 per share. CAC ¶¶ 22, 77; AGC ¶¶ 3, 57.

Five days later, on November 13, 2013, the FDA Advisory Committee released a “Background Package” on Lemtrada. CAC ¶ 23. It noted the concerns that the FDA had expressed to Genzyme between 2006 and 2011. *Id.* The same day, an FDA panel “took a series of seemingly contradictory votes.” *Id.* ¶ 78 (quoting a *Boston Globe* article).<sup>6</sup> These votes were purely advisory and were not binding on the FDA. *Id.* By a vote of 11 to 6, the panel adopted the view that the Lemtrada studies were biased because the patients had not been blinded. But by a vote of 12 to 6, the same panel accepted that Sanofi had provided substantial evidence of Lemtrada’s efficacy. Additionally, by a 17 to 0 vote, the panel affirmed that safety concerns should not preclude FDA approval of Lemtrada for patients for whom other drugs have not been

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<sup>6</sup> Some members abstained from some votes. *Id.*

effective. At the same time, however, the panel voted 16 to 0 that Lemtrada should not be approved as a “first-line treatment” for newly diagnosed MS patients. *Id.*

On December 27, 2013, the FDA notified Sanofi that the sBLA for Lemtrada had been rejected. CAC ¶ 25. Soon after, on December 30, 2013, Sanofi issued a press release stating that “Sanofi does not anticipate that the CVR milestone of U.S. approval of Lemtrada by March 31, 2014 will be met.” *Id.* ¶ 26; AGC ¶ 58. The press release explained that the “FDA has taken the position that Genzyme has not submitted evidence from adequate and well-controlled studies that demonstrate the benefits of Lemtrada outweigh its serious adverse effects.” AGC ¶ 58. That day, the market price of the CVRs dropped from \$0.77 to \$0.32 per share. CAC ¶ 26; AGC ¶ 58.

On January 23, 2014, Viehbacher gave an interview on Bloomberg Television in which he stated that the FDA rejection “wasn’t a total surprise.” CAC ¶ 27; AGC ¶¶ 5, 59. He explained that “when we acquired Genzyme, we actually created a contingent value right, recognizing that it was not going to be an easy thing to bring Lemtrada to the market. This is a drug that’s been in development for quite some time. That having been said, this is a drug that’s been approved by 30 countries in the world.” Def. Decl. Ex. 55, at 2.

## **5. Sanofi Announces FDA Approval of Lemtrada**

On April 7, 2014, following the filing of these lawsuits, Sanofi issued a press release stating that after “constructive discussions” with the FDA, it intended to resubmit the Lemtrada application. CAC ¶ 80.

On May 30, 2014, the company issued another press release stating that the FDA had accepted a resubmitted sBLA “based on data from the same clinical studies included in the original sBLA.” Def. Decl. Ex. 53, at 2. Over the next several months, Sanofi submitted more than two dozen amendments to its application. *See* 13 Civ. 8806, Dkt. 55, at 12.

Finally, on November 14, 2014, Sanofi announced that the FDA had approved Lemtrada for the treatment of certain MS patients, again based on data from the same clinical trials included in the original licensing application. *Id.* at 3, 7.<sup>7</sup>

## **B. Procedural History**

On December 11, 2013, plaintiff John Solak filed a Complaint on behalf of himself and all others similarly situated. 13 Civ. 8806, Dkt. 1. It alleged that Sanofi, through its executives, misrepresented the safety and efficacy of Lemtrada and failed to disclose flaws in the clinical trials that decreased the likelihood of obtaining timely FDA approval. *Id.* ¶¶ 9, 37. As a result of these materially misleading statements, Solak claimed, he and other members of the purported class had bought CVRs at artificially inflated prices, then lost money when the FDA issued its briefing report and the value of the CVRs declined. *Id.* ¶ 53. On this basis, Solak asserted claims under § 10b-5 and § 20(a) of the Exchange Act. *Id.* ¶¶ 54–69.

On December 18, 2013, Vincent Stasiulewicz filed a separate Complaint on behalf of himself and all others similarly situated. 13 Civ. 8991, Dkt. 1. Stasiulewicz’s Complaint was substantially similar to Solak’s: It alleged that Sanofi misled investors regarding Lemtrada’s safety and efficacy, the design of the clinical trials, and the likelihood of timely FDA approval. *Id.* ¶ 9. Sanofi thereby caused Stasiulewicz and other members of the purported class to purchase CVRs at artificially inflated prices. *Id.* ¶ 47. Like Solak, Stasiulewicz brought claims under claims under § 10b-5 and § 20(a) of the Exchange Act. *Id.* ¶¶ 45–60. The Court accepted Stasiulewicz’s case as related to Solak’s on January 23, 2014.

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<sup>7</sup> The Court takes judicial notice of the fact that Sanofi’s press releases “contained certain information, without regard to the truth of their contents.” *Staeher*, 547 F.3d at 425. Although the Court recites the fact of post-lawsuit FDA approval for completeness of the record, the fact of that later approval has no bearing on this decision.

On February 10, 2014, Solak moved to consolidate the two cases. 13 Civ. 8806, Dkt. 8–10; 13 Civ. 8891, Dkt. 3–5. On March 3, 2014, the Court granted the motion and consolidated the cases under the caption “In Re Sanofi Securities Litigation.” 13 Civ. 8806, Dkt. 27; 13 Civ. 8891, Dkt. 12.

On April 28, 2014, these plaintiffs filed a Consolidated Amended Complaint. 13 Civ. 8806, Dkt. 44 (“CAC”). The putative class consists of all persons, other than defendants, who purchased CVRs between March 6, 2012 and November 7, 2013. *Id.* ¶ 1. The CAC asserts claims under § 10b-5 and § 20(a) of the Exchange Act. *Id.* ¶¶ 100–15. As defendants, it names Sanofi, Viehbacher, Meeker, and Contamine. *Id.* ¶¶ 39–42.

On March 28, 2014, a group of 32 corporations (the “AG Funds plaintiffs”) filed a separate Complaint whose claims arose from the same events. 14 Civ. 2211, Dkt. 2 (“AGC”). The AG Funds plaintiffs either opted out of the class or acquired CVRs prior to the class period. *Id.* ¶¶ 7–13. The Court accepted this case as related to the pending consolidated class action. Like the CAC, the AGC brings claims under § 10(b) and § 20(a) of the Exchange Act. *Id.* ¶¶ 77–87. It also brings claims under § 18 of the Exchange Act, §§ 11 and 12 of the Securities Act, and various state blue sky laws. *Id.* ¶¶ 61–76, 88–106. The AGC names as defendants Sanofi, Genzyme, Viehbacher, Meeker, and Contamine (collectively, the “defendants”). *Id.* ¶¶ 14–18.

On June 27, 2014, defendants filed motions to dismiss both complaints, along with memoranda of law and supporting declarations. 13 Civ. 8806, Dkt. 48, 49 (“Def. Br.”), 50 (“Def. Decl.”); 14 Civ. 2211, Dkt. 17, 18, 19. Defendants argue, *inter alia*, that plaintiffs failed to identify an actionable misstatement or material omission and to adequately plead scienter. They argue that their statements were not misleading, but rather were either non-actionable expressions of historical fact, forward-looking statements accompanied by meaningful

cautionary language, permissible corporate puffery, or declarations of opinion that were sincerely and reasonably held. On August 26, 2014, plaintiffs filed their opposition to the motions to dismiss. 13 Civ. 8806, Dkt. 51 (“CA Br.”); 14 Civ. 2211, Dkt. 20 (“AG Br.”). On October 10, 2014, defendants filed replies. 13 Civ. 8806, Dkt. 52 (“Def. CA Reply”); 14 Civ. 2211, Dkt. 21 (“Def. AG Reply”). On October 31, 2014, the Court held argument. 14 Civ. 2211, Dkt. 24 (“Tr.”).

On November 17, 2014, defendants submitted a letter informing the Court that the FDA had approved Lemtrada. 13 Civ. 8806, Dkt. 55. On November 18, 2014, plaintiffs filed letters in reply. 13 Civ. 8806, Dkt. 56; 14 Civ. 2211, Dkt. 26.

## **II. Applicable Legal Principles**

### **A. Standard for Resolving the Motion to Dismiss**

To survive a motion to dismiss under Rule 12(b)(6), a complaint must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim will only have “facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A complaint is properly dismissed, where, as a matter of law, “the allegations in a complaint, however true, could not raise a claim of entitlement to relief.” *Twombly*, 550 U.S. at 558. Although the court must accept as true all well-pled factual allegations in the complaint and draw all reasonable inferences in the plaintiff’s favor, *Steginsky v. Xcelera Inc.*, 741 F.3d 365, 368 (2d Cir. 2014), that tenet “is inapplicable to legal conclusions,” *Iqbal*, 556 U.S. at 678.

“Securities fraud claims are subject to heightened pleading requirements that the plaintiff must meet to survive a motion to dismiss.” *ATSI Commc’ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d



87, 99 (2d Cir. 2007); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321–23 (2007). First, a complaint alleging securities fraud must meet the requirements of Federal Rule of Civil Procedure 9(b). *See ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009). Rule 9(b) states that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). “Allegations that are conclusory or unsupported by factual assertions are insufficient.” *ATSI*, 493 F.3d at 99.

Second, such a complaint must comply with the pleading requirements of the Private Securities Litigation Reform Act (“PSLRA”), 15 U.S.C. § 78u–4(b). *See ECA*, 553 F.3d at 196. In particular, where a plaintiff’s claims depend upon allegations that the defendant has made an untrue statement of material fact or that the defendant omitted a material fact necessary to make a statement not misleading, the plaintiff “shall specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.” 15 U.S.C. § 78u–4(b)(1). Thus, in order to plead a claim of securities fraud, plaintiffs “must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so.” *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004). In addition, the plaintiff “shall, with respect to each act or omission . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u–4(b)(2). “For an inference of scienter to be strong, ‘a reasonable person [must] deem [it] cogent and *at least as compelling* as any opposing inference one could draw from the facts alleged.’” *ATSI*, 493 F.3d at 99 (quoting *Tellabs*, 551 U.S. at 324) (alteration and emphasis in original).

## **B. Elements of Plaintiffs' Claims**

The class-action plaintiffs assert claims under §§ 10(b) and 20(a) of the Exchange Act. CAC ¶¶ 100–15. The AG Funds plaintiffs assert claims under those sections as well as § 18 of the Exchange Act, §§ 11 and 12(a)(2) of the Securities Act, and the blue sky laws of California, Massachusetts, and Minnesota. AGC ¶¶ 61–106.

To state a claim under § 10(b) of the Exchange Act, a plaintiff must adequately plead “(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.” *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1317 (2011) (citation omitted).

To state a claim under § 18 of the Exchange Act, a plaintiff must adequately plead that: “(1) the defendant made or caused to be made a statement of material fact that was false or misleading at the time and in light of the circumstances under which it was made, (2) the statement was contained in a document filed pursuant to the Exchange Act or any rule or regulation thereunder, (3) reliance on the false statement, and (4) resulting loss to the plaintiff.” *In re Adelphia Commc’ns Corp. Sec. & Derivative Litig.*, 542 F. Supp. 2d 266, 268 (S.D.N.Y. 2008) (citation omitted).

Claims brought under §§ 11 and 12(a)(2) of the Securities Act involve “roughly parallel elements.” *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 359 (2d Cir. 2010). “Section 11 imposes liability on issuers and other signatories of a registration statement that ‘contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading.’ 15 U.S.C. § 77k(a).

Section 12(a)(2) imposes liability under similar circumstances with respect to, *inter alia*, prospectuses. *Id.* § 771(a)(2).” *Fait v. Regions Fin. Corp.*, 655 F.3d 105, 109 (2d Cir. 2011).

Finally, to state a claim under § 20(a) of the Exchange Act, “a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person’s fraud.” *Carpenters Pension Trust Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 236 (2d Cir. 2014) (quoting *ATSI*, 493 F.3d at 108). If plaintiffs have not adequately alleged a primary violation, *i.e.*, a viable claim under another provision of the Securities Act or Exchange Act, then the § 20(a) claims must be dismissed.

Thus, common to *all* of plaintiffs’ claims—indeed, the central element—is the existence of a false or misleading statement or omission of material fact. *See City of Omaha, Neb. Civilian Employees’ Ret. Sys. v. CBS Corp.*, 679 F.3d 64, 67–68 (2d Cir. 2012) (“[T]hese claims all share a material misstatement or omission element.”). Additionally, scienter is an element of plaintiffs’ § 10(b) and § 20(a) claims under the Exchange Act. The Court highlights, and below addresses the allegations as to, these two elements because consideration of them is sufficient to establish that neither the CAC nor the AGC states a claim.

### **1. False or Misleading Statement or Omission**

As noted, for any of plaintiffs’ claims to survive the motions to dismiss, plaintiffs must have adequately pled “that the defendant made a statement that was ‘misleading as to a material fact.’” *Matrixx Initiatives*, 131 S. Ct. at 1318 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)) (emphasis omitted). Federal securities law “do[es] not create an affirmative duty to disclose any and all material information.” *Id.* at 1321. “Disclosure of information is not required . . . simply because it may be relevant or of interest to a reasonable investor.” *Resnick v.*

*Swartz*, 303 F.3d 147, 154 (2d Cir. 2002). Instead, an omission is actionable only when disclosure of information is “necessary ‘to make . . . statements made, in the light of the circumstances under which they were made, not misleading.’” *Matrixx Initiatives*, 131 S. Ct. at 1321 (quoting 17 C.F.R. § 240.10b–5(b)) (ellipses in original).

As for the materiality requirement, it “is satisfied when there is ‘a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available.’” *Id.* at 1318 (quoting *Basic*, 485 U.S. at 231–32). As the Supreme Court has explained, a lower standard—such as defining a “material fact” as any “fact which a reasonable shareholder *might* consider important”—would lead corporations to “bury the shareholders in an avalanche of trivial information[,] a result that is hardly conducive to informed decisionmaking.” *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448–49 (1976). The “materiality hurdle” is, therefore, “a meaningful pleading obstacle.” *In re ProShares Trust Sec. Litig.*, 728 F.3d 96, 102 (2d Cir. 2013). However, because of the fact-intensive nature of the materiality inquiry, the Court may not dismiss a complaint “on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance.” *Carpenters Pension Trust Fund*, 750 F.3d at 235 (quoting *ECA*, 553 F.3d at 197).

In contrast to objective statements of material fact, subjective statements of opinion are generally not actionable as fraud. *See, e.g., In re Nevsun Res. Ltd.*, No. 12 Civ. 1845 (PGG), 2013 WL 6017402, at \*9 (S.D.N.Y. Sept. 27, 2013). “Subjective statements can be actionable only if the ‘defendant’s opinions were both false and not honestly believed when they were made.’” *Kleinman v. Elan Corp.*, 706 F.3d 145, 153 (2d Cir. 2013) (quoting *Fait*, 655 F.3d at

113)); *see also, e.g., City of Omaha*, 679 F.3d at 67–68 (holding that this standard applies to claims brought under §§ 11, 12, 10(b), and 20(a) because they “all share a material misstatement or omission element”); *Freidus v. ING Groep N.V.*, 736 F. Supp. 2d 816, 836 (S.D.N.Y. 2010) (“That opinion can be false or misleading only if the opinion-giver . . . did not truly believe it to be the case at the time it was issued.”); *Fait v. Regions Fin. Corp.*, 712 F. Supp. 2d 117, 125 n.55 (S.D.N.Y. 2010) *aff’d*, 655 F.3d 105 (2d Cir. 2011) (collecting cases). “It is not sufficient for these purposes to allege that an opinion was unreasonable, irrational, excessively optimistic, [or] not borne out by subsequent events.” *In re Salomon Analyst Level 3 Litig.*, 350 F. Supp. 2d 477, 489 (S.D.N.Y. 2004). “The Second Circuit has firmly rejected this ‘fraud by hindsight’ approach.” *Podany v. Robertson Stephens, Inc.*, 318 F. Supp. 2d 146, 156 (S.D.N.Y. 2004) (citing *Stevelman v. Alias Research, Inc.*, 174 F.3d 79, 85 (2d Cir. 1999)). Rather, plaintiffs “must allege ‘with particularity’ ‘provable facts’ to demonstrate that the statement of opinion is both objectively and subjectively false.” *Bond Opportunity Fund v. Unilab Corp.*, No. 99 Civ. 11074 (JSM), 2003 WL 21058251, at \*5 (S.D.N.Y. May 9, 2003), *aff’d* 87 F. App’x 772 (2d Cir. 2004) (summary order) (quoting *Va. Bankshares v. Sandberg*, 501 U.S. 1083, 1093–98 (1991)).

## 2. Scierter

To sustain their § 10(b) and § 20(a) claims, plaintiffs must also adequately plead scierter. *See Matrixx Initiatives*, 131 S. Ct. at 1317; *Carpenter Pension Trust Fund*, 750 F.3d at 236.<sup>8</sup> As

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<sup>8</sup> Defendants argue that plaintiffs’ other federal claims “sound in fraud” and therefore also require proof of scierter. Def. Br. 31–32. That is wrong. *See, e.g., City of Pontiac Policemen’s & Firemen’s Ret. Sys.*, 752 F.3d at 182 (“plaintiffs need not allege scierter” to state claims under § 11 or § 12); *Special Situations Fund III QP, L.P. v. Deloitte Touche Tohmatsu CPA, Ltd.*, No. 13 Civ. 1094 (ER), 2014 WL 3605540, at \*26 (S.D.N.Y. July 21, 2014) (plaintiffs “need not allege scierter to state a claim under Section 18”). Claims that sound in fraud must satisfy the heightened pleading requirements of Rule 9(b), but that Rule does not add substantive elements such as scierter to any claim. *See Rombach*, 355 F.3d at 175 (“[W]hile a plaintiff need allege no

noted, Rule 9(b) and the PSLRA require plaintiffs to “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u–4(b)(2). “For an inference of scienter to be strong, ‘a reasonable person [must] deem [it] cogent and *at least as compelling* as any opposing inference one could draw from the facts alleged.’” *ATSI*, 493 F.3d at 99 (quoting *Tellabs*, 551 U.S. at 324) (alteration and emphasis in original).

The requisite mental state is one “embracing intent to deceive, manipulate, or defraud.” *Tellabs*, 551 U.S. at 319. Plaintiffs “may satisfy this requirement by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness.” *ATSI*, 493 F.3d at 99.

Recklessness is “a state of mind approximating actual intent, and not merely a heightened form of negligence.” *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009) (citation and emphasis omitted). To qualify as reckless, defendants’ conduct must have been “‘highly unreasonable’” and “‘an extreme departure from the standards of ordinary care.’” *Novak v. Kasaks*, 216 F.3d 300, 311 (2d Cir. 2000) (quoting *Rolf v. Blyth, Eastman Dillion & Co.*, 570 F.2d 38, 47 (2d Cir. 1978)). An alleged “refusal to see the obvious, or to investigate the doubtful” must be “egregious” to be actionable. *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 269 (2d Cir. 1996) (citation omitted). Further, where, as here, plaintiffs do not allege that defendants had a motive to defraud the public, they “must produce a stronger inference of recklessness.” *Kalnit v. Eichler*, 264 F.3d 131, 143 (2d Cir. 2001).

More concretely, plaintiffs can establish recklessness by adequately alleging that “defendants knew facts or had access to non-public information contradicting their public statements” and therefore “knew or should have known they were misrepresenting material

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more than negligence to proceed under Section 11 and Section 12(a)(2), claims that do rely upon averments of fraud are subject to the test of Rule 9(b).”).

facts.” *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 76 (2d Cir. 2001) (citing *Novak*, 216 F.3d at 308). “The key, of course, is the honest belief of the management in the truth of information issued to the public. If the management knows that certain facts will necessarily prevent the regulatory approval . . . and conceals these facts from the investing public, then there is scienter.” *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008) *aff’d sub nom. State Univ. Ret. Sys. of Ill. v. Astrazeneca PLC*, 334 F. App’x 404 (2d Cir. 2009) (summary order). Similarly, there is scienter “if the management is reckless in dealing with such adverse facts.” *Id.* If, on the other hand, “the management of the company releases positive reports about the drug to the public along the way which the management honestly believes to be true, and where there is no reckless disregard for truth, then that is not securities fraud.” *Id.*; *see also id.* (collecting cases).

### **C. PSLRA Safe Harbor**

The PSLRA amended both the Securities Act and the Exchange Act to provide a safe harbor for forward-looking statements. *See* 15 U.S.C. § 77z-2 (Securities Act); 15 U.S.C. § 78u-5(e) (Exchange Act). Forward-looking statements are defined as those that contain, among other things, “a projection of revenues, income, [or] earnings,” “plans and objectives of management for future operations,” or “a statement of future economic performance.” *Id.* Under these parallel statutory provisions, a forward-looking statement is not actionable if it “is identified and accompanied by meaningful cautionary language *or* is immaterial *or* the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading.” *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 766 (2d Cir. 2010). Because the statute is written in the disjunctive, statements are protected by the safe harbor if they satisfy any one of these three categories. *Id.* Materiality is defined above; the other two categories are defined as follows:

*Meaningful cautionary language:* To qualify as “meaningful,” cautionary language “must convey substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statements.” *Id.* at 771 (citing H.R. Conf. Rep. 104-369, at 43 (1995)). Language that is “vague” or “mere boilerplate” does not suffice. *Id.* at 772. “To determine whether cautionary language is meaningful, courts must first ‘identify the allegedly undisclosed risk’ and then ‘read the allegedly fraudulent materials—including the cautionary language—to determine if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist.’” *In re Delcath Sys., Inc. Sec. Litig.*, No. 13 Civ. 3116 (LGS), 2014 WL 2933151, at \*10 (S.D.N.Y. June 27, 2014) (quoting *Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 359 (2d Cir. 2002)). Plaintiffs may establish that cautionary language is not meaningful “by showing, for example, that the cautionary language did not expressly warn of or did not directly relate to the risk that brought about plaintiffs’ loss.” *Halperin*, 295 F.3d at 359.

*Actual knowledge:* The scienter requirement for forward-looking statements—actual knowledge—is “stricter than for statements of current fact. Whereas liability for the latter requires a showing of either knowing falsity or recklessness, liability for the former attaches only upon proof of knowing falsity.” *Slayton*, 604 F.3d at 773 (quoting *Inst. Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 274 (3d Cir. 2009)). And under the heightened pleading standards, which apply to both scienter requirements, plaintiffs must “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2). “For an inference of scienter to be strong, ‘a reasonable person [must] deem [it] cogent and *at least as compelling* as any opposing inference one could draw from the facts alleged.’” *ATSI*, 493 F.3d at 99 (quoting *Tellabs*, 551 U.S. at 324) (alteration and emphasis in original).



### **III. Analysis**

The two Complaints identify a total of 26 statements that plaintiffs allege are false or misleading.<sup>9</sup> Broadly speaking, these statements address four subjects: (1) the company’s view of the prospects of timely FDA approval of Lemtrada, (2) the timing of the anticipated launch of Lemtrada, (3) the results of the ongoing clinical trials, and (4) Lemtrada’s adverse effects on patients. Plaintiffs’ central grievance—the absence of any specific disclosure of the FDA’s concerns about the single-blind design of the Lemtrada clinical trials and the correspondingly heightened burden for obtaining FDA approval—is germane to most of these categories.

For the reasons that follow, the Court holds that the statements in the first two categories are not actionable because they are statements of opinion, and plaintiffs have not adequately pled that they were other than genuinely held when made. Such statements are therefore neither false nor misleading, nor made with scienter; they are also protected by the PSLRA safe harbor. The statements in the third and fourth categories are not actionable because they were not misleading as to material facts, and plaintiffs have not adequately alleged scienter, *i.e.*, that defendants either had a motive and opportunity to commit fraud or were reckless in making those statements.

#### **A. Statements Regarding the Prospect of FDA Approval of Lemtrada**

The AGC challenges six statements made in Genzyme’s or Sanofi’s SEC filings that address FDA approval of Lemtrada. *See* AGC ¶¶ 30, 40, 42, 43, 44, 52. Each statement is to the effect that the company expects the FDA to approve Lemtrada prior to March 31, 2014, the cutoff date for the first CVR payment milestone. Five of these statements are substantively identical: They represent that Genzyme “anticipates” or “expects” FDA approval of Lemtrada “in the second half of 2012” or, in one instance, that Sanofi “expects action” in 2013. *See id.*

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<sup>9</sup> The CAC lists 17 such statements. The AGC lists 12—three of which are common to the CAC and AGC, and nine of which are unique to the AGC. *See* CAC ¶¶ 45–73; AGC ¶¶ 30–52.

¶¶ 40, 42, 43, 44, 52. The sixth statement goes further: It forecasts a 90% likelihood of reaching the FDA approval milestone, an 80% likelihood of reaching the first sales milestone, a 54% likelihood of reaching the second sales milestone, and a 50% likelihood of reaching the third sales milestone. *Id.* ¶ 30. The AGC alleges that these statements were “misleading” because they “were not accompanied by any mention of the concerns the FDA had expressed about the trials or Lemtrada’s approval prospects.” AGC ¶¶ 30, 40, 42, 43, 44, 52.

### **1. False or Misleading Statement or Omission**

These six statements are statements of opinion—they express Sanofi’s expectations for the future rather than presently existing, objective facts. *See, e.g., In re Bank of Am. Corp. Sec., Derivative, & Employee Ret. Income Sec. Act (ERISA) Litig.*, No. 09 MD 2058 (PKC), 2013 WL 6504801, at \*16 (S.D.N.Y. Dec. 11, 2013) (prediction of a company’s future performance is a statement of opinion); *In re MF Global Holdings Ltd. Sec. Litig.*, 982 F. Supp. 2d 277, 312 (S.D.N.Y. 2013) (statement that a target is “more likely than not to be realized” is a statement of opinion). Accordingly, the statements are “actionable only if the ‘defendant’s opinions were both false and not honestly believed when they were made.’” *Kleinman*, 706 F.3d at 153 (quoting *Fait*, 655 F.3d at 113)).

On the facts pled and properly considered on a motion to dismiss, there is no basis to conclude that defendants did not genuinely believe what they were saying at the time they said it. Defendants’ business decisions strongly indicate that they regarded Lemtrada as a promising new drug: Sanofi paid \$20 billion to acquire Genzyme, CAC ¶ 8, in large part due to Genzyme’s ownership of Lemtrada, *see* CAC ¶ 6. And the two companies conducted the Lemtrada clinical trials over the course of a decade, presumably at significant cost. *See* AGC ¶ 36; CAC ¶ 23. Indeed, Sanofi told analysts that it continued to invest in Lemtrada even as it was “struggling to

fund everything [it had] in development” and “killed” other projects. Def. Decl. Ex. 61, at 17. Plaintiffs recite no facts indicating that defendants did not in fact expect FDA approval within the timeframe their statements articulated. And, absent concretely pled facts to this effect, the inference that the AG Funds plaintiffs ask the Court to draw—that Sanofi acquired Genzyme and continued to fund the Lemtrada clinical trials while secretly believing that FDA approval was unlikely, impossible, or, if achievable, only on a delinquent time schedule—is implausible and conjectural. *Cf. City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) (citing *Kleinman*, 706 F.3d at 153) (“[T]he initiation of Phase 3 cost millions of dollars and required FDA approval, rendering it improbable that defendants would have continued if they did not believe their interpretation of the interim results or if they thought the drug a complete failure.”); *Davidoff v. Farina*, No. 04 Civ. 7617 (NRB), 2005 WL 2030501, at \*11 n.19 (S.D.N.Y. Aug. 22, 2005) (“[I]t would have made no economic sense for defendants to invest literally billions of dollars in a venture that they knew would fail.”).

Seeking to sustain their position, the AG Funds plaintiffs focus on a single purported admission by one individual defendant: Sanofi CEO Viehbacher’s January 23, 2014 statement that the FDA’s decision to reject Lemtrada “wasn’t a total surprise.” AGC ¶¶ 5, 59; CAC ¶¶ 21, 27–29, 84. But Viehbacher’s asserted lack of “total surprise” is not inconsistent with defendants’ statements that they expected timely FDA approval. *Cf. In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 558 (S.D.N.Y. 2004) (“Given the uncertainty inherent in any application for FDA approval, Defendants’ alleged ‘inkling’ that the FDA might not approve the drug “is reasonable and entirely consistent with Defendants’ public statements.”). In fact, as pled, defendants projected a 10% likelihood that the FDA would not approve Lemtrada by March 31, 2014. *See* AGC ¶¶ 30, 34. An event or circumstance with a 10% possibility of coming to pass

can be fairly described as “not a total surprise”: Good examples from daily life include a rainout of a baseball game, a one-hour flight delay, or a first-place finish by a racehorse whose odds of winning had been 9:1. Thus, the AGC not only fails to afford a basis to infer that defendants did not sincerely believe their projections when they made them; it also indicates that defendants affirmatively put the market on notice of what they perceived to be a 10% chance that the FDA would not approve Lemtrada by the cutoff date for the milestone payment.

Additionally, examination of Viehbacher’s statement in the context in which it was made belies plaintiffs’ characterization of it as an admission that, before the FDA acted, he had viewed the likelihood of non-approval as higher than the company had forecast:

SCHATZKER: Lemtrada was a drug that you hoped to use to gain a fair amount of share, I think it’s fair to say, in the multiple sclerosis business. The FDA rejected it. How much of a letdown was the for you?

VIEHBACHER: Well, it’s actually something that wasn’t a total surprise, because when we acquired Genzyme, we actually created a contingent value right, recognizing that it was not going to be an easy thing to bring Lemtrada to the market. This is a drug that’s been in development for quite some time.

That having been said, this is a drug that’s been approved by 30 countries in the world. We’re seeing patients who have gone five years without a relapse. So we believe that the drug actually is working and it’s important for patients, and that’s why for the first time in my 25 years in this industry, we’re thinking about doing an appeal with the FDA.

Def. Decl. Ex. 55, at 2. Read in context, Viehbacher’s statement does not concede that he (and the company) knew all along that the FDA would reject Lemtrada. Rather, the statement admits no more than that the company regarded FDA approval as uncertain. That proposition is consistent with Sanofi’s public statements about Lemtrada’s prospects.

The CAC also recites statements attributed to a confidential witness (“CW”) who was employed by Genzyme between 2002 and 2012. *See* CAC ¶¶ 29–32. Although these statements are not alleged in the AGC, in the interest of completeness, the Court considers them in

evaluating the AG Funds plaintiffs' claim of falsity. The CAC alleges that, according to the CW, Genzyme and Sanofi employees were "aware of Lemtrada's (and the trials') shortcomings" and "were hypersensitive to reported adverse events" and the implications "for Lemtrada's ultimate commercial viability." CAC ¶ 29. The CW further reported that a Steering Committee composed of high-level Genzyme executives was "concerned with Lemtrada's safety profile." CAC ¶ 31. These allegations, however, are far too generic to give rise to a plausible inference that defendants did not believe their public predictions. Any responsible corporate executive would be "aware of" ongoing clinical trial results, "concerned" about adverse events, and "sensitive" to the possibility of FDA non-approval, whether its likelihood was appraised at 10%, higher, or lower. There is no inconsistency between a pharmaceutical company executive's concern about adverse events and the possibility of a negative FDA reaction to a proposed drug, and his sincere optimism that the FDA was likely to approve the drug.

Even assuming the AG Funds plaintiffs had adequately pled subjective falsity, the statements in question also have to be objectively false to be actionable. *Fait*, 655 F.3d at 110. In arguing that defendants' stated optimism was incompatible with the facts known to them, the AG Funds plaintiffs emphasize that the FDA had repeatedly criticized the single-blind design of the Lemtrada clinical trials—a critique that defendants never publicly disclosed. AG Br. 1–2; *see also* CA Br. 1. But again, viewed in context, the FDA's statements to the company could readily be squared with the company's publicly anticipated timetable for approval. As pled, in expressing misgivings about a single-blind methodology, the FDA did not state that it would refuse to approve Lemtrada were this methodology used. It stated instead that, to obtain approval, Lemtrada's demonstrated "treatment effect" would have to be large—*i.e.*, the company would carry a heavier burden of proof than if a double-blind approach had been used—to

compensate for the bias potentially introduced by a single-blind methodology. *See* AGC ¶ 36; CAC ¶ 23; *see also* Def. Decl. Ex. 11 (FDA briefing report).

Further, a series of actions by the FDA, as reflected in plaintiffs' pleadings and in public filings, communicated that timely agency approval *was* possible. Despite the concerns the FDA had expressed about the design of the clinical trials, it allowed those trials to proceed. Had the FDA at any point concluded that there were "serious defects in study design that would render the study incapable of producing valid evidence of safety and effectiveness," it had "authority to issue a clinical hold." 52 Fed. Reg. 8798. Clinical holds protect human subjects from exposure to flawed and therefore scientifically worthless studies. *Id.* Indeed, after a patient died of sepsis in 2005, the FDA had placed Lemtrada's Phase II clinical trials on hold. *See* AGC ¶ 36(d); CAC ¶ 31. But, approximately 10 months later, the FDA removed that hold and at no later point halted the Lemtrada studies. *See* AGC ¶ 36(e); CAC ¶ 31. On the contrary, the FDA permitted Genzyme to commence Phase III studies. *See* AGC ¶¶ 43, 44, 46; CAC ¶ 12. Phase III trials may be performed only "after preliminary evidence suggesting effectiveness of the drug has been obtained." 21 C.F.R. § 312.21(c). Accordingly, this step "can only be taken after there have been positive Phase 2 results sufficient to satisfy both business and regulatory interests." *Kleinman*, 706 F.3d at 153. The FDA then placed the Phase III studies on a fast track. AGC ¶ 42; Def. Decl. Ex. 32, at 12. This procedure, too, was consistent with Sanofi's stated perception that timely FDA approval was likely, as it is "designed to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening and severely debilitating illnesses." 21 C.F.R. § 312.80. Finally, in January 2013, the FDA accepted Sanofi's sBLA seeking approval for Lemtrada. AGC ¶ 50; CAC ¶¶ 18, 61.

In light of these actions, and the absence of allegations of concrete facts that put defendants on notice that timely FDA approval was unlikely, the AG Funds plaintiffs have failed to adequately plead that defendants' stated opinion that timely FDA approval was likely was "objectively false." *Fait*, 655 F.3d at 110.

## 2. **Scienter**

As Judge Lynch has aptly observed, where plaintiffs allege a false statement of opinion, "the falsity and scienter requirements are essentially identical" because "a material misstatement of *opinion* is by its nature a false statement, not about the objective world, but about the defendant's own belief." *Podany*, 318 F. Supp. 2d at 154. Thus, defendants act with scienter "[i]f the management knows that certain facts will necessarily prevent the regulatory approval . . . and conceals these facts from the investing public." *AstraZeneca*, 559 F. Supp. 2d at 470. But there is no scienter if "the management of the company releases positive reports about the drug to the public along the way which the management honestly believes to be true, and where there is no reckless disregard for truth." *Id.*

Here, for much the same reasons that the AG Funds plaintiffs have failed to adequately plead falsity with respect to defendants' projections about FDA approval, they also fail to adequately plead scienter. The AG Funds plaintiffs emphasize that defendants knew about the design shortcomings in the Lemtrada clinical trials and the heightened burden of proof that followed from it, yet failed to disclose that interim feedback, and were aware or recklessly failed to appreciate that the absence of such a disclosure made their optimistic projections about FDA approval false and misleading. *See* AGC ¶¶ 79–80; CAC ¶¶ 81–84. But the inference of scienter does not follow from the fact of non-disclosure. The law did not impose an affirmative duty to disclose the FDA's interim feedback just because it would be of interest to investors, *see*

*Resnick*, 303 F.3d at 154, and “[t]he mere allegation that defendants failed to disclose [relevant information] does not in and of itself constitute strong evidence that they did so with scienter,” *Fort Worth Employers’ Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 226 (S.D.N.Y. 2009).

Instead, to adequately plead scienter, plaintiffs must also provide sufficient factual allegations to indicate that defendants understood that their public statements were inaccurate, or were “highly unreasonable” in failing to appreciate that possibility. *Novak*, 216 F.3d at 308. For the reasons noted earlier, the AGC and CAC do not clear this hurdle. The complaints do not plead a factual basis on which the Court can infer that defendants did not believe their statements about the likelihood of timely FDA approval. And the FDA’s statements and actions known to defendants were by no means inconsistent with defendants’ stated optimism. Viewing the circumstances, as pled, in totality, an inference of scienter is not plausible, and the inference that defendants intended to mislead is not “at least as compelling” as the alternative inference, namely, “that defendants did not know, and had no reason to know, that the FDA would initially” reject the sBLA for Lemtrada. *Biovail*, 615 F. Supp. 2d at 228.

### **3. PSLRA Safe Harbor**

The PSLRA safe harbor presents a final barrier to sustaining the AG Funds plaintiffs’ challenge to this first category of statements.

The six statements about FDA approval are classically forward-looking—they address what defendants expected to occur in the future. *See Kovtun v. VIVUS, Inc.*, No. 10 Civ. 4957 (PJH), 2012 WL 4477647, at \*12 (N.D. Cal. Sept. 27, 2012) (“Projections about the likelihood of FDA approval are forward-looking statements.”); *see also, e.g., Delcath*, 2014 WL 2933151, at \*10; *City of Livonia Employees’ Ret. Sys. v. Wyeth*, No. 07 Civ. 10329 (RJS), 2010 WL 3910265, at \*5 (S.D.N.Y. Sept. 29, 2010). Accordingly, apart from plaintiffs’ failure to



adequately allege a misleading statement or scienter, these statements are not actionable if they are covered by any of the three disjunctive categories established by the PSLRA safe harbor. *See* 15 U.S.C. § 78u-5(c); *Slayton*, 604 F. 3d at 766 (A forward-looking statement is not actionable if it “is identified and accompanied by meaningful cautionary language *or* is immaterial *or* the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading.”). The statements at issue here are covered by the first and third of these categories.

First, the complaints do not adequately allege that the statements were “made with actual knowledge that [they were] false or misleading.” 15 U.S.C. § 78u-5(c)(1)(B). The AGC contains only a conclusory allegation that defendants “engaged in deceptive conduct knowingly and intentionally *or* in such a reckless manner as to constitute willful deceit and fraud.” AGC ¶ 80 (emphasis added). Similarly, the AG Funds plaintiffs’ brief pursues a theory of “conscious recklessness” to establish the scienter element of the § 10(b) claim. *See* AG Funds Br. 19–21; *id.* at 19 (“[D]efendants knew *or, more importantly, should have known* that they were misrepresenting material facts.”) (emphasis added).<sup>10</sup> But, as reviewed above, the allegations in the AGC, considered as a whole, do not support an inference of recklessness, much less a “strong inference” of actual knowledge. *Slayton*, 604 F. 3d at 773.

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<sup>10</sup> In a brief footnote, the AG Funds plaintiffs argue that Genzyme had a motive to commit fraud, namely, to complete the merger with Sanofi and reap a large profit. AG Br. 20 n.12. As the Second Circuit has held, however, “the desire to achieve the most lucrative acquisition proposal can be attributed to virtually every company seeking to be acquired. Such generalized desires do not establish scienter.” *Kalnit*, 264 F.3d at 141. And this motive is not logically attributed to Sanofi and its executives, who, by this theory, were victims of Genzyme’s fraud. This motive also does not logically apply to statements made after the acquisition was completed in 2011.

Second, each forward-looking statement was identified as such and accompanied by cautionary language. *See* Def. Decl. Exs. 5, 30, 31, 32, 33.<sup>11</sup> The Form 10-K Genzyme filed on March 1, 2011, is illustrative. There, Genzyme stated that it “anticipate[s] product approval in the United States in the second half of 2012.” Def. Decl. Ex. 32, at 12. The filing identifies such statements as forward-looking, *id.* at 4, and includes a substantial section on “risk factors,” *id.* at 23–40. That section states, in relevant part:

[A] regulatory authority may deny or delay an approval because it was not satisfied with the structure or conduct of clinical trials or due to its assessment of the data we supply. A regulatory authority, for instance, may not believe that we have adequately addressed negative safety signals. Clinical data are subject to varied interpretations, and regulatory authorities may disagree with our assessments of data.

*Id.* at 26–27. This language explicitly identifies the salient risk, namely, that a regulatory authority such as the FDA could deny or delay approval of Lemtrada. It also identifies “important factors that could cause actual results to differ,” *Slayton*, 604 F.3d at 768, for instance, because the FDA might take issue with the structure of the clinical trials or find the resulting data less compelling than Genzyme does.

Similarly, the Form 14D–9 filed on March 7, 2011 projects a 90% likelihood of achieving the FDA approval milestone, which required obtaining FDA approval of Lemtrada by March 31, 2014. Def. Decl. Ex. 31, at 45. The relevant section goes on to state, however, that “[t]he Projections, while presented with numerical specificity, necessarily were based on numerous variables and assumptions that are inherently uncertain and many of which are beyond the control of the Company’s management,” including “regulatory conditions,” “the timing of regulatory approvals,” and the “success of clinical testing.” *Id.* “Accordingly, there can be no

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<sup>11</sup> Genzyme’s Form 14D–9 filed on March 7, 2011 contains two distinct allegedly actionable statements. *See* ACG ¶¶ 30, 40. Both appear in the excerpt of the 14D–9 attached to defendants’ declaration as Exhibit 31.

assurance that the Projections will be realized.” *Id.* at 46. An earlier section of the 14D–9, entitled “risk and uncertainty associated with the CVRs,” is equally explicit: “The milestone payments, if any, under the CVRs are uncertain and subject to the risk that Sanofi and its affiliates may not achieve any of the CVR milestones, including . . . timely FDA approval” of Lemtrada. *Id.* at 27.

These statements conveyed substantive information about the risk that ultimately materialized. As such, they were meaningful cautionary language, not mere boilerplate. Compare *Ill. State Bd. of Inv. v. Authentidate Holding Corp.*, 369 F. App’x 260, 264 n.3 (2d Cir. 2010) (summary order) (warning that forward-looking statements were “subject to certain risks and uncertainties” was boilerplate), with *Halperin*, 295 F.3d at 360 (warning that securities were not presently and might not ever be registered for resale was meaningful cautionary language, not boilerplate). Courts have found that similar language “adequately disclosed the possibility of a risk that materialized when the FDA denied approval.” *Delcath*, 2014 WL 2933151, at \*10. In *Delcath*, for example, Judge Schofield found that “no reasonable investor would have been misled about the nature of the risk” because defendants had cautioned the public “that the FDA may not ‘deem [the] product candidate to be adequately safe and effective,’ may not ‘find the data from . . . clinical trials to be sufficient to support a claim of safety and efficacy,’ and . . . may ‘interpret data . . . significantly differently than [the Company did].’” *Id.* (alterations and first and third omissions in original). And in *Biovail*, Judge McMahon held that defendants’ warnings that “forward-looking statements involve risk and uncertainties” and that “the difficulty of predicting” regulatory approvals “could cause actual results to differ materially from these expectations” sufficed to “indisputably satisfy the PSLRA safe harbor.” *Biovail*, 615 F. Supp. 2d

at 232–33. Thus, the six statements regarding FDA approval are protected by two independent prongs of the PSLRA safe harbor.

### **B. Statements Regarding the Launch of Lemtrada**

While the AG Funds plaintiffs challenge statements that addressed the likelihood of FDA approval of Lemtrada, most of which predated the class period, the class-action plaintiffs attack five purportedly actionable statements that discuss the launch of Lemtrada more generally. *See* CAC ¶¶ 56, 57, 63, 70, 73. For example, during an October 25, 2012 conference call, Sanofi CFO Contamine told analysts that Sanofi was “prepar[ing]” for “the launch of Lemtrada,” CAC ¶ 56, and Sanofi CEO Viehebacher stated that he was “actually very satisfied with where the progress is going,” *id.* ¶ 57. Similarly, during conference calls on February 7, 2013 and May 3, 2013, Viehbacher told analysts that Sanofi had “significant new medicines” entering “a market of some \$14 billion worldwide.” *Id.* ¶ 63; *see also id.* ¶ 70 (“We’ve got Lemtrada that can start to roll out in the EU, and we expect a decision on Lemtrada by the end of the year. I mean, if you have two big products rolling out into a \$14 billion market, that is something that we don’t have today.”). Finally, on October 30, 2013, Viehebacher reiterated that he was “feeling pretty, pretty relaxed,” in part because Sanofi had “Aubagio and Lemtrada rolling out.” *Id.* ¶ 73.

To the extent these statements reflect objective facts—*i.e.*, that defendants were “prepar[ing]” for “the launch of Lemtrada” in late 2012, CAC ¶ 56, and that Lemtrada was “rolling out” in late 2013, *id.* ¶ 73—they are neither false nor misleading. By the end of 2013, Lemtrada had been approved for marketing and distribution in the European Union, Canada, and Australia. *Def. Decl. Exs. 45, 48, 49.* In early 2014, Lemtrada was also approved in Mexico and Brazil. *Id. Exs. 50, 51.* Accordingly, although the United States “accounts for 20% of MS

patients worldwide,” CAC ¶ 11, the drug was in fact launching in dozens of other countries. The class-action plaintiffs do not plead facts to the contrary.

To be sure, “[s]ome statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors.” *McMahan v. Warehouse Ent., Inc.*, 900 F.2d 576, 579 (2d Cir. 1990). But, as pled, such is not the case here. The statements at issue are couched in general terms and make no concrete representations about product launch in the United States. Their only specific references are to the global market. See CAC ¶ 63 (“This is a market of some \$14 billion worldwide.”); *id.* ¶ 70 (“I mean, if you have two big products rolling out into a \$14 billion market, that is something we don’t have today.”). As such, the omission of specific statements that the FDA had made did not render these statements misleading. Rather, the statements served to “accurately inform rather than mislead prospective buyers,” *McMahan*, 900 F.2d at 579, and the pleadings give the Court no basis on which to infer that they were made in bad faith.

To the extent the statements on which the class-action plaintiffs seize articulate subjective opinions—*i.e.*, that defendants felt “relaxed,” CAC ¶ 73, and “satisfied,” CAC ¶ 57, and “expect[ed] a decision on Lemtrada [by the FDA] by the end of the year,” CAC ¶ 70—they are not actionable for much the same reason as the statements pertaining to FDA approval challenged in the AGC. The CAC does not adequately plead that defendants’ opinions were objectively unreasonable or were not honestly believed when stated. The CAC thereby fails to plead both the false statement and scienter elements of its various claims. See *Kleinman*, 706 F.3d at 153; *Podany*, 318 F. Supp. 2d at 154. Similarly, these five statements are protected by the PSLRA safe harbor. They are forward-looking in that they voice defendants’ expectations regarding Lemtrada’s debut into the global market. See *Shemian v. Research In Motion Ltd.*, No.

11 Civ. 4068 (RJS), 2013 WL 1285779, at \*24 (S.D.N.Y. Mar. 29, 2013), *aff'd*, 570 F. App'x 32 (2d Cir. 2014) (summary order) (discussing “forward-looking statements, such as planned product launches”). And, although these statements were not uniformly accompanied by cautionary language, plaintiffs do not allege concrete factual particulars that support an inference that the statements were “made with actual knowledge that [they were] false or misleading.” 15 U.S.C. § 78u-5(c)(1)(B). The CAC, like the AGC, instead alleges only that defendants were aware of the FDA’s concerns and therefore “knew *or* were severely reckless in disregarding” the misleading nature of their statements. CAC ¶ 84 (emphasis added); *see also id.* ¶¶ 81–83.

### C. Statements Regarding Lemtrada Clinical Trial Results

The third category of challenged statements consists of 13 statements describing—and lauding—the substantive results of the Lemtrada clinical trials. Both sets of plaintiffs claim that these statements are actionable. *See* CAC ¶¶ 45, 47, 49, 52, 59, 61, 64, 66, 68, 71; AGC ¶¶ 46, 47, 48, 49, 50, 51.<sup>12</sup> The statements in the March 7, 2013 Form 20–F are representative:

The two pivotal Phase III studies demonstrating the safety and efficacy of alemtuzumab [*i.e.*, Lemtrada] were completed in 2011 and the results were published in the *Lancet* in November 2012. The first study, CARE-MS I, demonstrated strong and robust treatment effect on the relapse rate co-primary endpoint vs Rebif in treatment-naïve MS patients. The co-primary endpoint of disability progression (time to sustained accumulation of disability: SAD) did not meet statistical significance. The second study, CARE-MS II, demonstrated that relapse rate and SAD were significantly reduced in MS patients receiving alemtuzumab as compared with Rebif in MS patients who had relapsed on prior therapy. Results from CARE-MS II also showed that patients treated with Lemtrada™ were significantly more likely to experience improvement in disability scores than those treated with Rebif, suggesting a reversal of disability in some patients. In both pivotal studies, safety results were consistent with previous

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<sup>12</sup> Four of these statements address both the results of clinical trials and Lemtrada’s side effects; they are therefore included in both the third and fourth categories of statements. *See* CAC ¶ 45 and AGC ¶ 47; CAC ¶ 52 and AGC ¶ 49; CAC ¶ 64; CAC ¶ 66 and AGC ¶ 51. Seven challenged statements appear only in the CAC, *see* CAC ¶¶ 47, 49, 59, 61, 64, 68, 71; three appear only in the AGC, *see* AGC ¶¶ 46, 48, 50; the remaining three appear in both complaints, *see* CAC ¶ 45 and AGC ¶ 47; CAC ¶ 52 and AGC ¶ 49; CAC ¶ 66 and AGC ¶ 51.

alemtuzumab use in MS and adverse events continued to be manageable. Marketing applications for Lemtrada™ are currently under review by regulatory authorities.

CAC ¶ 66; AGC ¶ 51.

Other challenged statements about the clinical trial results represented that Lemtrada had a “strong and robust treatment effect,” CAC ¶ 45; AGC ¶ 47; “significantly slowed” the accumulation of disability, CAC ¶ 47, *see also* CAC ¶ 59; AGC ¶ 48; and “significantly reduced relapse rates,” CAC ¶ 64. And others expressed personal enthusiasm: Genzyme President and CEO Meeker stated that he was “very pleased” with the “unprecedented” results, AGC ¶ 46, which “underscore the tremendous promise that Lemtrada holds for MS patients,” CAC ¶ 68; *see also* CAC ¶ 52; AGC ¶ 49 (“Lemtrada, given its efficacy and unique dosing schedule, has the potential to transform the lives of patients with Multiple Sclerosis.”). Similarly, Sanofi CEO Viehbach called the results “the best efficacy data that anybody has ever demonstrated in a product,” CAC ¶ 71, “nothing short of stunning,” CAC ¶ 49. Plaintiffs also challenge defendants’ statements that, based on these favorable results, they were “on track” to submit Lemtrada for FDA approval, AGC ¶¶ 46, 48, and later that they had submitted the sBLA, CAC ¶¶ 61, 64; AGC ¶ 50.

Both groups of plaintiffs argue that these statements were misleading because, while lauding the clinical trial results, defendants did not disclose that the FDA had expressed concerns about the single-blind study design such that a particularly strong treatment effect was required for approval. *See, e.g.*, CAC ¶ 23. The class-action plaintiffs argue that defendants should have disclosed that “there were material design issues and the presence of bias in the trials that prevented reliance on their results” and that they “lacked evidence from adequate and well controlled studies to support the effectiveness of Lemtrada for treating [MS].” CAC ¶ 48. Similarly, the AG Funds plaintiffs argue that the statements about the trial results and prospects

of FDA approval were misleading because they were “not accompanied by any mention of the concerns the FDA had expressed about the trials or Lemtrada’s approval prospects.” AGC ¶ 46.

It is undisputed that defendants never disclosed the specific FDA feedback cited in the CAC and AGC, including the reservations the agency expressed about the trials’ single-blind methodology and the heightened treatment effect the company would need to show to secure Lemtrada’s approval. *See* Tr. 10. However, defendants defend this omission as non-actionable, on several grounds. They argue: that (1) non-disclosure of the FDA’s feedback did not render the company’s statements materially misleading, particularly in light of case law rejecting securities fraud claims based on a company’s failure to disclose interim FDA feedback; (2) many of the challenged statements were non-actionable expressions of opinion; and (3) plaintiffs have not adequately pled scienter. The Court addresses these arguments in turn.

### **1. Misleading Omission of Material Fact**

In considering whether defendants were required to disclose the FDA’s feedback about the company’s testing methodology to make the company’s statements about Lemtrada non-misleading, context is important. In particular, much of the information conveyed to Sanofi by the FDA was publicly available.<sup>13</sup> And the FDA feedback specific to the Lemtrada clinical trials was part of an ongoing conversation with the agency that defendants had no affirmative legal duty to disclose.

Here, the FDA had publicly stated, including in federal regulations, its preference for double-blind studies. The federal regulation governing “adequate and well-controlled studies” states that “[a]ctive treatment trials,” the type of trial used to test Lemtrada, “usually include

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<sup>13</sup> On a motion to dismiss, the Court may consider “information already in the public domain and facts known or reasonably available to the shareholders.” *Rodman v. Grant Found.*, 608 F.2d 64, 70 (2d Cir. 1979).



randomization and blinding of patients or investigators, or both.” 21 C.F.R. § 314.126(b)(2)(iv); *see also, e.g., id.* § 314.126(b)(2) (blinding expected for placebo concurrent control and dose-comparison concurrent control studies); *id.* § 352.72(e) (sunscreen testing should be blinded); *id.* § 514.117(b)(7) (blinding preferred in studies of veterinary medications). The agency had also explained, in federal regulations and elsewhere, why it prefers this clinical testing methodology: “Blinding is intended to minimize the potential biases resulting from differences in management, treatment, or assessment of patients, or interpretation of results that could arise as a result of subject or investigator knowledge of the assigned treatment.” FDA Guidance for Industry at 4; *see also, e.g.,* 21 C.F.R. § 314.126(b)(5) (“An adequate and well-controlled study has the following characteristics . . . Adequate measures are taken to minimize bias on the part of the subjects, observers, and analysts of the data. The protocol and report of the study should describe the procedures used to accomplish this, such as blinding.”). The importance of blinding is among the “principles [that] have been developed over a period of years and are recognized by the scientific community as the essentials of a well-controlled clinical investigation.” 21 C.F.R. § 860.7(f). As such, the FDA considers the “[l]evel and methods of ‘blinding’” to determine whether data qualifies as “valid scientific evidence” that “provide[s] reasonable assurance that the device is safe and effective for its intended uses.” *Id.*

That the Lemtrada clinical trials used a single-blind, not double-blind, design was also well known. From at least June 2009 through November 2012, it was disclosed in a publicly available online database maintained by the National Institute of Health (“NIH”). *See* Def. Decl. Ex. 12, at 2 (“Study Design . . . Single Blind”); Ex. 21, at 2 (same); Ex. 22, at 2 (same). The Lemtrada study design was discussed in greater detail in the articles published in prominent medical journals, *The New England Journal of Medicine* and *The Lancet*. *See id.* Ex. 17, at 15

(“The infusion-related syndrome associated with [Lemtrada] precluded double-blinding.”); Ex. 28, at 3, 9 (similar); Ex. 29, at 4 (similar). Press releases attached to SEC filings also noted that patient treatment groups were “randomized” and that “evaluating neurologists . . . were blinded to the patients’ treatment assignments.” *Id.* Ex. 26, at 7; Ex. 27, at 9.

Given this publicly available information, a reasonable investor had reason to know that the design of the Lemtrada clinical trials fell short of the FDA’s gold standard. Such an investor could reasonably infer that the study design might impede or delay FDA approval. An investor could also reasonably infer that, as the FDA had told Genzyme, the FDA might require a more compelling showing than it would have required from a double-blind study to overcome the limitations of the sub-optimal study design. And indeed, during a call with analysts, defendants acknowledged that if Lemtrada was “going to come to market, they had to have an extremely convincing set of results.” Def. Decl. Ex. 59, at 5. Although not attributing that sentiment to the FDA, that statement fairly captured the FDA’s admonition to the company—that given its use of a single-blind clinical testing methodology, a particularly large treatment effect on MS patients would be required to secure FDA approval.

The issue, then, is whether omission of the FDA’s statements to Genzyme about the burden of proof it bore as a result of using the single-blind methodology “significantly altered the total mix of information made available” to investors. *Matrixx Initiatives, Inc.*, 131 S. Ct. at 1318 (citation omitted). Measured against a substantial body of case law, the answer is no.

The decision in *Kleinman v. Elan Corp.*, 706 F.3d 145 (2d Cir. 2013), is particularly instructive. At issue there was a press release reporting the results of clinical trials for an Alzheimer’s disease drug. *Id.* at 147–49. The press release called the results “encouraging” and disclosed that the “statistically significant and clinically meaningful benefits” had been shown

through “post-hoc analyses.” *Id.* at 149. Plaintiffs alleged that the press release was misleading because it failed to mention that the company’s methodology deviated from the FDA’s preferred approach. As plaintiffs alleged, the press release failed to reveal that “the post-hoc analysis was curvilinear,” and that defendants had been “able to tout positive results only because they deviated from the established protocol (which called for a linear analysis) and changed the metrics by which the data was analyzed.” *Id.* at 154. Notwithstanding this omission, the district court granted defendants’ motion to dismiss, and the Second Circuit affirmed. *Id.* at 147. The Second Circuit noted that: (1) the “press release accurately disclosed that the only positive results from the entirety of the Phase 2 study stemmed from the use of post-hoc analysis,” and (2) “when it is clear that post-hoc analysis is being used, it is understood that those results are less significant and should therefore have less impact on investors,” in significant part because publicly available FDA guidance had “cautioned” that conclusions about safety and efficacy based solely on post-hoc analyses are “unlikely to be accepted.” *Id.* at 154–55 & n.11. The press release was, therefore, not “false or misleading to a reasonable investor.” *Id.* at 156.

The analysis in *Kleinman* points to the same result here. Although defendants certainly could have reported the FDA’s statements about its preferred testing methodology and the implications for the company’s burden of proof, the failure to disclose those statements was not “false or misleading to a reasonable investor.” *Id.* Importantly, the FDA’s methodological commentary cannot be fairly depicted—as plaintiffs characterize it—as tantamount to a statement that Lemtrada could not or would not obtain timely FDA approval. The FDA statements to Genzyme recounted in the CAC and AGC do not say that. Taken on their face, those statements explained that a heightened showing of proof was needed to compensate for the less reliable testing methodology used. The public, through published FDA regulations and

guidance, was already on notice that the FDA preferred a double-blind methodology. Since it was “accurately disclosed” that the positive results of the Lemtrada clinical trials stemmed from a single-blind study, it was “understood that those results [were] less significant” than results from a double-blind study would have been. *Id.* at 154–55.

Furthermore, in a series of cases, courts have rejected claims of material omissions where pharmaceutical companies did not reveal procedural or methodological commentary, or other interim status reports, received from the FDA as to drugs under review. *See, e.g., In re MELA Sciences, Inc. Sec. Litig.*, No. 10 Civ. 8774 (VB), 2012 WL 4466604, at \*13–14 (S.D.N.Y. Sept. 19, 2012) (no duty to disclose FDA feedback expressing concerns about ongoing clinical trials); *Biovail*, 615 F. Supp. 2d at 231 (no duty to disclose FDA feedback critical of the design of an ongoing study); *Johnson v. Pozen Inc.*, No. 07 Civ. 599 (WXD), 2009 WL 426235, at \*19 (M.D.N.C. Feb. 19, 2009) (no duty to disclose “every detail of [defendant’s] FDA correspondence,” including certain safety concerns); *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. 04 Civ. 1030 (RPM), 2005 WL 4161977, at \*7 (D. Colo. Oct. 20, 2005) (no duty to disclose FDA questions and concerns about defendants’ analysis of clinical trial results); *In re Alkermes Sec. Litig.*, No. 03 Civ. 12091 (RCL), 2005 WL 2848341, at \*16 (D. Mass. Oct. 6, 2005) (no duty to disclose the fact that the FDA had requested additional studies); *In re Biogen Sec. Litig.*, 179 F.R.D. 25, 37 (D. Mass. 1997) (finding, at summary judgment, no duty to disclose FDA’s reservations about a drug’s efficacy); *Robbins v. Moore Med. Corp.*, 894 F. Supp. 661, 671 (S.D.N.Y. 1995) (finding, at summary judgment, no duty to disclose details of an ongoing FDA review of a drug’s “recipe”); *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953,

966 (D. Md. 1995) (no duty to disclose the FDA’s questions about a clinical trial design).<sup>14</sup>

Analogously, courts have held that there is no duty to disclose the results of FDA inspections that do not reflect final agency determinations. *See, e.g., Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 52 (2d Cir. 1995); *In re Genzyme Corp.*, No. 09 Civ. 11299 (GAO), 2012 WL 1076124, at \*10 (D. Mass. Mar. 30, 2012); *City of Pontiac Gen. Employees’ Ret. Sys. v. Stryker Corp.*, 865 F. Supp. 2d 811, 825 (W.D. Mich. 2012); *Monk v. Johnson & Johnson*, No. 10 Civ. 4841 (FLW), 2011 WL 6339824, at \*13 (D.N.J. Dec. 19, 2011); *Anderson v. Abbott Labs.*, 140 F. Supp. 2d 894, 902 (N.D. Ill.) *aff’d sub nom. Gallagher v. Abbott Labs.*, 269 F.3d 806 (7th Cir. 2001).

These courts reasoned that interim FDA feedback is not material because it does not express a binding agency decision and is subject to change as the FDA and pharmaceutical companies work together to develop viable clinical trials and approvable licensing applications. In *Medimmune*, for example, the court recognized that “[c]ontinuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process.” 873 F. Supp. at 966. Problems, issues, and questions arise “in random or sporadic fashion,” and those questions tend to “get answered in the process.” *Id.* This case comfortably fits that profile. As alleged here, the FDA’s position evolved over time: In 2002, the FDA told ILEX that the single-blind study “*will not* provide substantial support” for an application for approval of Lemtrada. AGC ¶ 36(a) (emphasis added). In 2004, the FDA told ILEX that the proposed

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<sup>14</sup> Even *In re Amylin Pharmaceuticals, Inc. Sec. Litig.*, No. 01 Civ. 1455 (BTM) (NLS), 2005 WL 21500525 (S.D. Cal. May 1, 2003), which held that defendants’ omissions of interim FDA feedback rendered their optimistic statements about FDA approval misleading, recognized that “[a] company seeking FDA approval of a new drug clearly is not under any obligation to disclose every single issue raised by the FDA throughout the process.” *Id.* at \*8. Rather, “if the FDA expresses significant concerns regarding the sufficiency of the trials, the company cannot make affirmative representations regarding the completeness or sufficiency of the trials without full disclosure.” *Id.* Here, in contrast to *Amylin*, the FDA expressed concerns about defendants’ methodology but took no position as to the sufficiency of the clinical trial data.

single-blind, small-sample-size study “is *unlikely* to provide substantial support” for an application. *Id.* ¶ 36(b) (emphasis added). But in 2006, although the FDA continued to note that “they *prefer* double-blinded, controlled studies, especially for the pivotal trials,” it also stated that “a rater blinded (but patient not blinded) study *may be adequate* if the effect is large.” CAC ¶ 23(a) (emphasis added). And by January 2011, the FDA primarily “emphasize[d] the importance of presenting a full discussion and analysis of the impact of having the patients and treating physicians unblinded.” *Id.* ¶ 23(d). Defendants had no duty to disclose these ongoing discussions with the FDA. *See Medimmune*, 873 F. Supp. at 966.

The class-action plaintiffs argue that finding no material misrepresentation here requires crediting a “truth on the market defense,” whereas such defenses are “generally inappropriate for resolution on a motion to dismiss.” CA Br. 16. That is incorrect. “Under the ‘truth on the market’ theory, ‘a misrepresentation is immaterial if the information is already known to the market because the misrepresentation cannot then defraud the market.’” *In re Bank of Am. Corp. Sec., Derivative, & Employee Ret. Income Sec. Act (ERISA) Litig.*, 757 F. Supp. 2d 260, 301 (S.D.N.Y. 2010) (quoting *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 167 (2d Cir. 2000)). The core of a “truth on the market defense” is that defendants’ misrepresentations could not have “affected stock price, because the truth already was known.” *Id.* at 301–02. Here, however, defendants do not argue that the public was aware of the FDA’s interim feedback to the company. Rather, defendants’ argument is that that feedback, considered in light of what was undisputedly publicly known, was not material and thus not legally required to be disclosed. *See Abely v. Aeterna Zentaris Inc.*, No. 12 Civ. 4711 (PKC), 2013 WL 2399869, at \*12 (S.D.N.Y. May 29, 2013) (finding that defendants had not asserted a “truth-on-the-market defense” where

they “d[id] not contend that, for example, the market was aware of the Phase 2 results . . . but rather, that they were under no obligation to release that data”).

Finally, contrary to plaintiffs’ theory, *see* CA Br. 2; AG. Br. 2, the eventual sharp drops in price of the CVRs on November 8, 2013 and December 30, 2013 cannot be taken as evidence of the materiality of the undisclosed FDA commentary. Based on the pleadings and cognizable public statements, the drops in price of the CVRs did not follow disclosure of the FDA’s concerns about the single-blind study design. Rather, the prices dropped after the FDA issued a report that “sharply criticized” Sanofi’s application for FDA approval of Lemtrada in a way tantamount to “rejection of Sanofi’s submission,” CAC ¶¶ 19, 22; *see also* AGC ¶ 55, and again after the FDA formally declined to approve the drug, CAC ¶ 26; AGC ¶¶ 3, 58. That information—that the Advisory Committee had reached negative view of the sBLA, and that the FDA rejected the sBLA for Lemtrada three months before the March 31, 2014 cutoff—was new to the market and to defendants alike. And it is well-settled that, under the securities laws, “[c]orporate officials need not be clairvoyant; they are only responsible for revealing those material facts reasonably available to them.” *Novak*, 216 F.3d at 309.

## **2. Statements of Opinion**

Many of the 13 statements addressing Lemtrada’s clinical trial results are unambiguously statements of opinion. In them, the defendants subjectively assessed the clinical trial results and described them as encouraging. *See, e.g.*, CAC ¶¶ 45, 66 (discussing the “strong and robust treatment effect”); AGC ¶¶ 47, 51 (same). They also reported their personal reactions to the data. *See, e.g.*, CAC ¶ 68 (“These results underscore the tremendous promise that Lemtrada holds for MS patients.”); AGC ¶ 46 (“We are very pleased with the results of the CARE-MS II study.”). Courts have repeatedly held “publicly stated interpretations of the results of various

clinical studies” to be “opinions” because “[r]easonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.” *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 567 & n.20 (S.D.N.Y. 2011); *see also, e.g., Abely*, 2013 WL 2399869, at \*12; *MELA Sciences*, 2012 WL 4466604, at \*13. Such statements are actionable only if they were “both false and not honestly believed when they were made.” *Kleinman*, 706 F.3d at 153.

As discussed at pages 26–31, *supra*, plaintiffs’ pleadings do not come close to supplying a factual basis on which to conclude that defendants disbelieved their own statements. And the surrounding circumstances strongly undermine any such thesis: Defendants’ substantial investment of money and personnel in the Lemtrada clinical trials over a several-year period is hard to square with the premise that defendants understood that the study design was fatally flawed or that the results made Lemtrada dead on arrival. By far the most logical inference on the facts pled—indeed, the only plausible inference—is that defendants (1) sincerely held their optimistic views of the clinical trial results, and (2) were surprised and disappointed by the FDA’s temporary—for the FDA eventually reversed course—rejection of these results as inadequate.

The facts on which plaintiffs rely are not to the contrary. For the reasons explained above, Viehbacher’s statement that the FDA’s initial decision was not a “total surprise,” and the testimony of a confidential witness, do not support the inference that before the FDA’s decision, either company or any individual defendant expected a rejection or viewed the clinical trial results ominously. Absent “some particularized facts to indicate that” defendants “held a private opinion different from [their] public opinions,” plaintiffs’ allegations “are simply insufficient to state a claim for securities fraud.” *Salomon*, 350 F. Supp. 2d at 493.



As to objective falsity, based on the pleadings, defendants' expressed opinions had an ample basis in fact. Although the FDA had expressed concerns about the design of the Lemtrada clinical trials, it allowed those trials to proceed to Phase III, the final phase, and even placed the Phase III studies on a fast track. *See* CAC ¶¶ 30–32; AGC ¶¶ 42–44. Moreover, while voting against FDA approval of Lemtrada, the FDA Advisory Committee adopted the view that Sanofi had provided substantial evidence of Lemtrada's efficacy by a vote of 12 to 6. CAC ¶ 78. Further, articles published in peer-reviewed medical journals and regulatory decisions approving Lemtrada for sale in more than 30 countries supported defendants' interpretations of the study results. *See AstraZeneca*, 559 F. Supp. 2d at 470 (“[O]ther facts, such as the approval of [the drug] in Europe for some uses, made it not unreasonable for defendants to believe in their product.”). Plaintiffs therefore cannot plausibly contend that defendants' opinions were “without any reasonable basis,” *In re AnnTaylor Stores Sec. Litig.*, 807 F. Supp. 990, 1000 (S.D.N.Y. 1992) (citing *Va. Bankshares*, 501 U.S. at 1090–91) (emphasis omitted), or were “objectively false,” *Fait*, 655 F.3d at 110.

### **3.     Scienter**

Even assuming *arguendo* that defendants' statements about the Lemtrada clinical trial results were materially misleading because they failed to report the FDA's comments about the implications of using a single-blind testing methodology, the CAC and AGC do not plausibly allege that those statements were made with “intent to deceive, manipulate, or defraud.” *Tellabs*, 551 U.S. at 319.

Again, plaintiffs claim that defendants knowingly or recklessly failed to disclose the FDA's interim feedback. *See* CA Br. 27–32; AG Br. 19–21. Plaintiffs can establish conscious recklessness by adequately alleging that “defendants knew facts or had access to non-public

information contradicting their public statements” and therefore “knew or should have known they were misrepresenting material facts.” *Scholastic*, 252 F.3d at 76 (citing *Novak*, 216 F.3d at 208). But, as noted, the FDA’s comments simply did not contradict Sanofi’s public statements.<sup>15</sup> The FDA had informed defendants that “a rater blinded (but patient not blinded) study may be adequate if the effect is large. However, a totally blinded study is more likely to be found persuasive if the treatment effect is relatively small.” CAC ¶ 23(a); *see also* CAC ¶¶ 23(b)–(d); AGC ¶¶ 36(e)–(g). Accordingly, while voicing a strong preference for a double- rather than single-blind clinical trial design, *see* CAC ¶ 23; AGC ¶ 36, the FDA did not take any position as to the adequacy of the emerging study data when measured against the standard of proof applicable to single-blind test results.

Nor do the facts alleged support that defendants were “highly unreasonable” in failing to disclose the FDA’s concerns. *See Novak*, 216 F.3d at 308. The gravity of the FDA’s negative feedback was muted by a series of encouraging regulatory decisions—to lift the clinical hold placed after a patient died of sepsis, *see* CAC ¶ 31; AGC ¶ 36(e); to allow the clinical trials to proceed to Phase III, *see* CAC ¶ 12; AGC ¶¶ 43, 44, 46; to place the Phase III clinical trials on a

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<sup>15</sup> In their brief, the class-action plaintiffs claim that the FDA was *unwilling* to accept results from a single-blind trial. CA Br. 24. But that characterization distends the facts pled. As alleged, the FDA “strongly recommend[ed]” conducting a double-blind study but affirmed that “robust” results from a single-blind trial could “overcome these issues” and support FDA approval of Lemtrada. CAC ¶ 23. Had the FDA told the company that approval was impossible given the single-blind methodology—essentially, giving advance notice of Lemtrada’s certain rejection—Sanofi’s failure to disclose that feedback while touting its optimism about FDA approval would have assuredly been a material omission. *See, e.g., In re Transkaryotic Therapies, Inc. Sec. Litig.*, 319 F. Supp. 2d 152, 159 (D. Mass. 2004) (claim adequately pled where defendants failed to disclose FDA feedback that the “studies did not show efficacy and were methodologically flawed and that in order to generate acceptable data, [defendant] would have to start over from scratch”); *In re Amylin Pharms., Inc.*, No. Civ. 1455 (BTM) (NLS), 2002 WL 31520051, at \*4 (S.D. Cal. Oct. 10, 2002) (claim adequately pled where defendants failed to disclose FDA feedback that “the current study data is not considered pivotal data” and therefore could not support FDA approval).

fast track, *see* AGC ¶ 42; and to accept the sBLA for review, *see* CAC ¶¶ 18, 61; AGC ¶ 50. The interim feedback, viewed in real time, was about methodology and process, not about the FDA’s eventual decision. As such, the significance of that feedback became apparent only after the FDA had released its briefing report and its decision not to approve Lemtrada. “Whether Sanofi’s optimism was, by hindsight, unwarranted ‘do[es] not give rise to securities violations’ because ‘[u]p to a point, companies must be permitted to operate with a hopeful outlook.’” *Sanofi-Aventis*, 774 F. Supp. 2d at 566 (quoting *Rombach*, 355 F.3d at 174); *see also, e.g., Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129–30 (2d Cir. 1994) (“People in charge of an enterprise are not required to take a gloomy, fearful or defeatist view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business that they manage.”). At all relevant times, and without the benefit of hindsight, Sanofi did not have reason to know that its public statements omitted or misrepresented material facts.

Finally, based on the facts alleged, the inference of scienter is by no means “at least as compelling” as the “opposing inference of nonfraudulent intent.” *Tellabs*, 551 U.S. at 314. Defendants, acting with FDA authorization, conducted the Lemtrada clinical trials over a period of years and consistently reported favorable results. *See* CAC ¶¶ 13–17; AGC ¶¶ 42–52. The most plausible inference is, therefore, that defendants honestly believed their descriptions of the data and did not anticipate that the FDA would adopt a different view. The unfavorable FDA briefing report and approval decision, released after defendants made the statements now at issue, does not undermine this conclusion. *Cf. AstraZeneca*, 559 F. Supp. 2d at 471 (“It is impossible to read the FDA document and the AstraZeneca document without concluding that both present the honest analysis and conclusions of their authors.”).

#### **D. Statements Regarding Lemtrada’s Side Effects**

The final category of challenged statements consists of six statements about Lemtrada’s side effects. *See* CAC ¶¶ 45, 50, 52, 54, 64, 66; AGC ¶¶ 47, 49, 51.<sup>16</sup> Four represented that “safety results” and “adverse effects” were “consistent” across trials and were “manageable.” CAC ¶¶ 45, 52, 64, 66; AGC ¶¶ 47, 49, 51. One further reported that “infusion-associated reactions and infections . . . were generally mild to moderate in severity.” CAC ¶ 52, AGC ¶ 49. Another reported Viehbacher’s perspective of the results: During an April 27, 2012 conference call, Viehbacher stated that “I think this is going to be a major drug. People are concerned about safety, but I don’t see the reason for that.” CAC ¶ 50.<sup>17</sup> Plaintiffs argue that these statements are actionable because defendants omitted the fact that Lemtrada “presented serious and potentially fatal side effects.” *See, e.g.*, CAC ¶ 51.

##### **1. False or Misleading Statement or Omission**

Physicians involved in the Lemtrada studies published full results of the Phase II clinical trial in *The New England Journal of Medicine* on October 23, 2008—years before any of the allegedly misleading statements were made. Def. Decl. Ex 17. This publication disclosed every adverse event that had been observed in the clinical trials, from the most minor (*e.g.*, headache, chills) to the most serious (*e.g.*, cancer, abnormal liver function). *See id.* at 11–14. It also

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<sup>16</sup> Two statements address only Lemtrada’s side effects, *see* CAC ¶¶ 50, 54; the other four address both side effects and the results of the clinical trials. Three of the four statements that fall into both categories appear in both the CAC and the AGC, *see* CAC ¶ 45 and AGC ¶ 47, CAC ¶ 52 and AGC ¶ 59, CAC ¶ 66 and AGC ¶ 51; the others of the challenged six statements appear only in the CAC, *see* CAC ¶¶ 50, 54, 64.

<sup>17</sup> The class-action plaintiffs also allege that, on July 26, 2012, Viehbacher stated that “the fact that we have this strong safety profile is extremely important.” CAC ¶ 54. This statement is non-actionable for the reasons discussed below. It also was not made in reference to Lemtrada: As the transcript of the July 26, 2012 earnings conference call reveals, this statement referred to a dengue vaccine. *See* Def. Decl. Ex. 39, at 22.

discussed the “difficult issue of exposing young adults who have little disability to a drug having potentially serious side effects,” *id.* at 15, and straightforwardly acknowledged that “[t]here were two deaths, both in the [Lemtrada] group,” *id.* at 11.

After Sanofi completed the Phase III clinical trials in 2012, researchers published a similarly comprehensive report in *The Lancet*, another well-known medical journal. *See* Def. Decl. Exs. 28–29. In the interim, Genzyme and Sanofi released updated safety information on an annual basis. *See id.* Exs. 18 (2010), 24–26 (2011), 27 (2012), 30 (2013).

Plaintiffs do not allege that these publicly available reports omitted any adverse events that had been observed, or that these reports were otherwise incomplete.<sup>18</sup> Instead, plaintiffs argue that the brief synopses of Lemtrada’s safety profile included in Sanofi’s SEC filings and discussed during conference calls were misleading because those statements did not fully explain Lemtrada’s “serious and potentially fatal side effects.” *See, e.g.*, CAC ¶ 51.

Considering defendants’ statements in the aggregate, however, plaintiffs have not adequately alleged that defendants made any actionable omissions. “[T]he ‘total mix’ of information made available,” *Matrixx Initiatives*, 131 S. Ct. at 1318 (citation omitted), included that Lemtrada “presented serious and potentially fatal side effects.” Defendants were not obliged to reproduce a comprehensive enumeration of adverse events every time they mentioned Lemtrada’s safety profile. *Cf. Abuhamdan v. Blyth, Inc.*, No. 12 Civ. 1597 (MPS), 2014 WL 1289251, at \*9 (D. Conn. Mar. 31, 2014) (“Defendants had no duty to disclose the allegedly omitted information . . . because they had already disclosed substantially similar information,

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<sup>18</sup> This comprehensive disclosure also distinguishes this case from *Amylin*, *supra* notes 13 and 14, on which plaintiffs heavily rely. In *Amylin*, defendants “reported that successful results were obtained without an increase in severe hypoglycemic events,” when in fact the drug “appeared to increase the risk of severe hypoglycemia.” *Amylin*, 2002 WL 31520051, at \*5. These statements were held to be “misleading because a reasonable investor would believe that ‘no’ severe hypoglycemia means ‘no’ severe hypoglycemia.” *Id.* at \*6.

thus making all of the identified statements not misleading.”). Although the complete disclosures were important when made in the first instance, a reasonable investor would not expect repetition at every opportunity. And the securities laws do not require such regurgitation; that approach would “bury the shareholders in an avalanche of trivial information.” *TSC Indus.*, 426 U.S. at 448. The CAC and AGC thus do not adequately allege a materially false or misleading statement or omission with respect to Lemtrada’s side effects.

Most statements regarding Lemtrada’s side-effects—for instance, that adverse events were “manageable,” CAC ¶ 64, “mild to moderate in severity,” CAC ¶ 52; AGC ¶ 49, and not a cause for concern, CAC ¶ 50—are also non-actionable as expressions of opinion. *See, e.g., In re Pfizer, Inc. Sec. Litig.*, 538 F. Supp. 2d 621, 634 (S.D.N.Y. 2008) (defendants’ statements regarding the seriousness of a drug’s side-effects were statements of opinion). Plaintiffs have not adequately alleged that these opinions were other than sincerely held. And various facts cognizable on a motion to dismiss—for instance, that the FDA Advisory Committee unanimously found that safety concerns should not preclude FDA approval of Lemtrada for patients for whom other drugs have not been effective, CAC ¶ 78, and that more than 30 countries had approved Lemtrada by early 2014, Def. Decl. Exs. 45, 48–51—underscore that defendants’ stated views were objectively reasonable. *See Kleinman*, 706 F.3d at 153.

## **2.     Scienter**

Again, plaintiffs have not adequately alleged that Sanofi’s statements about Lemtrada’s side effects were made with the “intent to deceive, manipulate, or defraud.” *Tellabs*, 551 U.S. at 319. Unlike with the category of statements pertaining to the clinical trial results, plaintiffs do not even allege that defendants had access to information about Lemtrada’s side-effects that was not made public. This makes an inference of conscious recklessness particularly hard to sustain.

*See Scholastic*, 252 F.3d at 76. The most plausible inference, instead, is benign: that defendants believed that they had reported all observed adverse events and felt no need to repeat that exhaustive disclosure in every later statement. The contrary inference—that defendants knew or should have known that they were misleadingly downplaying the seriousness of Lemtrada’s side-effects—is purely speculative. On the facts pled, it is nowhere near “*at least as compelling*” as the benign inference. *Id.* (quoting *Tellabs*, 551 U.S. at 324).

### **E. State Law Claims**

In addition to bringing federal claims, the AGC alleges violations of the blue sky laws of California, Massachusetts, and Minnesota. AGC ¶¶ 61–106. Because the AG Funds plaintiffs do not seek to proceed as a class—and those plaintiffs, even if treated as a class, number fewer than 100 members—the Class Action Fairness Act (“CAFA”) does not provide this Court with original jurisdiction over the AGC’s state-law claims. *See* 28 U.S.C. § 1332. Accordingly, having dismissed all federal law claims, the Court must determine whether to exercise supplemental jurisdiction over the remaining state law claims.

Federal district courts have supplemental jurisdiction over state-law claims “that are so related to” federal claims “that they form part of the same case or controversy.” 28 U.S.C. § 1367(a). However, such jurisdiction is “discretionary,” *City of Chicago v. Int’l Coll. of Surgeons*, 522 U.S. 156, 173 (1997), and a district court “may decline to exercise supplemental jurisdiction over a claim” if it “has dismissed all claims over which it has original jurisdiction,” 28 U.S.C. § 1367(c). A district court should, in deciding whether to exercise its supplemental jurisdiction, balance the traditional “values of judicial economy, convenience, fairness, and comity.” *Carnegie–Mellon Univ. v. Cohill*, 484 U.S. 343, 350 (1988). Both the Second Circuit and the Supreme Court have held that, as a general rule, “when the federal claims are dismissed

the ‘state claims should be dismissed as well.’” *In re Merrill Lynch Ltd. P’ships Litig.*, 154 F.3d 56, 61 (2d Cir. 1998) (quoting *United Mine Workers v. Gibbs*, 383 U.S. 715, 726 (1966)). The ordinary case “will point toward declining jurisdiction over the remaining state-law claims.” *Id.* (citing *Cohill*, 484 U.S. at 350 n. 7).

Here, no circumstances counsel in favor of exercising supplemental jurisdiction over the AG Funds plaintiffs’ state law claims. The Court has not invested the resources necessary to resolve these non-federal claims, and convenience, fairness, and comity do not require the Court to exercise supplemental jurisdiction. The Court accordingly declines to exercise supplemental jurisdiction over these claims. These claims are, therefore, dismissed without prejudice.

#### **F. Leave to Amend**

Federal Rule of Civil Procedure 15(a)(2) provides that leave to amend a complaint shall be “freely” given when “justice so requires,” although “a district court has discretion to deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party.” *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007). Granting leave to amend is “futile” if a revised claim still “could not withstand a motion to dismiss pursuant to Rule 12(b)(6).” *Dougherty v. Town of N. Hempstead Bd. of Zoning Appeals*, 282 F.3d 83, 88 (2d Cir. 2002). Where the problems with a claim are “substantive” rather than the result of an “inadequately or inartfully pleaded” complaint, an opportunity to replead would be “futile” and “should be denied.” *Cuoco v. Moritsugu*, 222 F.3d 99, 112 (2d Cir. 2000).

The deficiencies in both the CAC and AGC are substantive. The statements plaintiffs identify were not false or misleading. And the facts alleged in the complaints support the conclusion that defendants sincerely and reasonably believed their statements to be true. An amended complaint is therefore unlikely to survive a motion to dismiss.

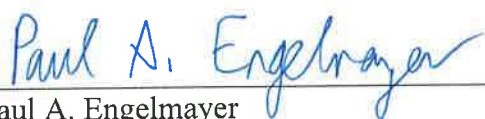


Further, there is no realistic prospect of rehabilitating plaintiffs' federal claims. This case has been vigorously litigated; the class-action plaintiffs have already availed themselves of one opportunity to amend their complaint, *see* 13 Civ. 8806, at Dkt. 44 (Amended Complaint); and neither set of plaintiffs has requested a further opportunity to amend. "In the absence of any identification of how a further amendment would improve upon the Complaint, leave to amend must be denied as futile." *In re WorldCom, Inc. Sec. Litig.*, 303 F. Supp. 2d 385, 391 (S.D.N.Y. 2004); *see also, e.g., Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 347 F. App'x 617, 622 (2d Cir. 2009) (summary order) ("Granting leave to amend is futile if it appears that plaintiff cannot address the deficiencies identified by the court and allege facts sufficient to support the claim.").

#### CONCLUSION

For the foregoing reasons, the Court hereby dismisses both complaints in their entirety, with prejudice as to all federal law claims. The Clerk of Court is respectfully directed to terminate all pending motions and to close these cases.

SO ORDERED.

  
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Paul A. Engelmayer  
United States District Judge

Dated: January 28, 2015  
New York, New York