RECOMMENDED FOR FULL-TEXT PUBLICATION
Pursuant to Sixth Circuit I.O.P. 32.1(b)

File Name: 18a0220p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

KEVIN L. DOUGHERTY,

Plaintiff,

RONALD E. WALLACE and WALTER J. MINETT, individually and on behalf of all others similarly situated,

Movants-Appellants,

v.

ESPERION THERAPEUTICS, INC.; TIM M. MAYLEBEN,

Defendants-Appellees.

No. 17-1701

Appeal from the United States District Court
for the Eastern District of Michigan at Detroit.
No. 2:16-cv-10089—Arthur J. Tarnow, District Judge.

Argued: March 15, 2018

Decided and Filed: September 27, 2018

Before: SILER, BATCHELDER, and DONALD, Circuit Judges.

COUNSEL

ARGUED: Steven F. Hubachek, ROBBINS GELLER RUDMAN & DOWD LLP, San Diego, California, for Appellants. Deborah S. Birnbach, GOODWIN PROCTER LLP, Boston, Massachusetts, for Appellees. **ON BRIEF:** Steven F. Hubachek, ROBBINS GELLER RUDMAN & DOWD LLP, San Diego, California, for Appellants. Deborah S. Birnbach, Kevin P. Martin, Adam Slutsky, Joshua J. Bone, GOODWIN PROCTER LLP, Boston, Massachusetts, for Appellees.

OPINION

SILER, Circuit Judge. Plaintiffs in securities-fraud suits are subject to a more onerous pleading burden than the average plaintiff. They must plead, among other things, a "strong inference of scienter" that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Doshi v. Gen. Cable Corp.*, 823 F.3d 1032, 1039 (6th Cir. 2016) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007)). In this case, the district court held that Plaintiffs, certain stockholders of Esperion Therapeutics, failed to adequately plead a strong inference that Esperion CEO Tim Mayleben willfully or recklessly made misleading statements to investors following a meeting with the FDA regarding the company's new cholesterol drug. Because Plaintiffs adequately alleged scienter, we REVERSE and REMAND.

I.

Esperion is a pharmaceutical company that was formed in 2008. Since its incorporation, Esperion has neither sold any products nor generated any revenue, relying instead upon investor funding. Esperion's sole focus is the development of ETC-1002, a first-in-class oral medication designed to lower LDL-cholesterol, also known as "bad cholesterol." Elevated LDL-cholesterol is a significant risk factor in cardiovascular disease and contributes to plaque deposits in arteries, which in turn cause heart attacks, strokes, and other medical issues. According to the Centers for Disease Control, approximately seventy-one million adults in the United States have elevated LDL-cholesterol levels.

The current standard of care for patients with high cholesterol is a family of drugs called statins. However, the use of statins is accompanied by a number of possible side effects—muscle pain or weakness, memory loss, and increased glucose levels, to name a few. Esperion estimates that between two and seven million American adults are statin-intolerant due to these side effects.

Compared to statins, ETC-1002 acts at an earlier point in the body's synthesis of cholesterol and avoids the muscle pain and weakness that statins produce in some patients. Esperion hopes to market ETC-1002 as an alternative treatment for statin-intolerant patients. Additionally, ETC-1002 could be used as an add-on therapy for patients who suffer from heterozygous familial hypercholesterolemia (HeFH) and clinical atherosclerotic cardiovascular disease (ASCVD). Patients with those conditions are often unable to reach their recommended LDL-cholesterol levels using statins alone, so the addition of ETC-1002 to their course of treatment might help those patients reach their cholesterol-level goals.

To that end, Esperion sought FDA approval for ETC-1002. Any new drug must be put through a series of clinical trials before it can be marketed and sold in the United States. Following initial testing on animals, pharmaceutical companies must seek permission from the FDA to test the new drug on humans. *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 39 (1st Cir. 2008) (citations omitted). If approved by the FDA, human clinical trials proceed in three phases:

> Phase I studies generally involve twenty to eighty subjects, and are designed to determine how the drug works in humans and the side effects associated with increasing doses. [21 C.F.R.] § 312.21(a)(1). Phase II studies usually involve no more than several hundred subjects, and are designed to evaluate the effectiveness of the drug, as well as common short-term side effects and risks. *Id.* § 312.21(b). Phase III studies are large-scale trials, usually involving several hundred to several thousand subjects, and are intended to gather the information necessary to provide an adequate basis for labeling the drug. *Id.* § 312.21(c). . . . After Phase III, the FDA considers the results of all of the clinical trials in determining whether to approve a drug for market. *See id.* §§ 314.125(b), 314.126(a).

Id.

By August 2015, Esperion had completed three Phase 1 studies and seven Phase 2 studies. In each trial, Esperion reported that ETC-1002 was well-tolerated in the study population and demonstrated significant average LDL-cholesterol reductions. That month, Esperion executives met with FDA officials for an "End-of-Phase 2 Meeting" to elicit feedback and advice regarding the path forward with Phase 3 of the approval process.

Following the meeting, Esperion published a press release on August 17, 2015, that contains two statements worth noting. First, the company stated that "[t]he FDA confirmed that LDL-C remains an acceptable clinical surrogate endpoint for the approval of an LDL-C lowering therapy such as ETC-1002 in patient populations who have a high unmet medical need, including patients with [HeFH] . . . or [ASCVD]." Second, the company said that, "[b]ased upon feedback from the FDA, approval of ETC-1002 in the HeFH and ASCVD patient populations will not require the completion of a cardiovascular outcomes trial."

These statements require some explanation to be fully understood in context. A cardiovascular outcomes trial (CVOT) is a costly, lengthy study that measures a drug's effectiveness in reducing cardiovascular risk over several years. Because lower LDL-cholesterol is presumed to improve overall heart health, the FDA does not typically require companies seeking approval of a new cholesterol-lowering drug to complete a CVOT and prove that the drug actually reduces cardiovascular risk. Instead, the FDA treats LDL-cholesterol as a "surrogate endpoint," or proxy, for cardiovascular risk. In other words, if a new drug is shown to lower LDL-cholesterol, the FDA assumes that it also improves overall cardiovascular health. By saying that the FDA would continue to use LDL-cholesterol as a proxy for cardiovascular risk, and that the FDA would not require a completed CVOT prior to approving ETC-1002, Esperion was essentially telling its investors that ETC-1002 had a clear path to regulatory approval.

In a follow-up conference call with market analysts, CEO Tim Mayleben stated that Esperion issued the release "because we felt that some of the information we learned last week at our End-of-Phase II meeting about the regulatory path forward for [ETC-]1002 was important for you to know sooner rather than later, even though we don't yet have meeting minutes back from the FDA." Regarding the possibility of a CVOT, Mayleben said that "[w]e know that [ETC-]1002 will not require a CV outcomes trial to be completed prior to approval in patients with heterozygous FH and ASCVD, those patient populations that the FDA considers to have an appropriate benefit/risk ratio." Thus, Mayleben confirmed what Esperion had stated in its earlier press release—the company believed the FDA would not require a completed CVOT prior to approval of ETC-1002 for use in patients whose high cholesterol could not be managed using statins alone. However, Mayleben indicated that the company still intended to conduct a CVOT

at some point, in hopes that the FDA would later approve ETC-1002 for broader use in patients seeking an overall reduction in the risk of cardiovascular disease.

During his conference call, Mayleben stressed the importance of receiving the FDA's final minutes from the meeting. He declined to fully answer several questions asked by participants in the conference call, saying that answers would have to wait until Esperion received the final minutes. And when Mayleben was asked how the FDA's minutes might differ from Esperion's notes from the meeting, he said that "we can't comment until we receive the final minutes from the FDA next month because . . . we have [zero] interest in front running the FDA on this. The FDA's minutes are the only minutes that matter, and so we're going to wait for those minutes."

Esperion's press release also included cautionary language, warning investors that the release "contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws," and suggesting that "Esperion may need to change the design of its Phase 3 program once final minutes from the FDA meeting are received."

Market reaction was mostly positive following the press release and conference call. Some analysts were disappointed that the proposed study population for Esperion's Phase 3 trials was narrower than anticipated. However, most analysts focused on the fact that, according to Esperion, the FDA was not planning to require a completed CVOT as a prerequisite to approval for ETC-1002's use in the high-unmet-need patient population.

Following its receipt of the final FDA minutes, Esperion published another press release on September 28, 2015. Contrary to its August statements, Esperion said that the "FDA has encouraged the Company to initiate a cardiovascular outcomes trial promptly, which would be well underway at the time of the New Drug Application submission and review, since any concern regarding the benefit/risk assessment of ETC-1002 could necessitate a completed cardiovascular outcomes trial before approval." In a subsequent conference call, Mayleben acknowledged that this language was "slightly different" than the language used in the company's August statements. Mayleben explained that this difference "reflects . . . as I was highlighting earlier about LDL as an accepted surrogate [and] whether it will continue to be an

accepted surrogate. I think it highlights the dynamic nature of this therapeutic area." Market analysts seized on this change in position, and Esperion's stock dropped 48% the next day, from $35.09 per share to $18.33 per share.

Plaintiffs, the purchasers of Esperion common stock between August 18 and September 28, brought this class action against Esperion and Mayleben for violating §§ 10(b) and 20(a) of the Securities Exchange Act of 1934, as well as SEC Rule 10b-5. Their amended complaint alleges that Esperion misled investors by falsely stating that the FDA would not require a completed CVOT prior to approval of ETC-1002, causing Esperion stock to trade at artificially inflated levels during the class period. When the FDA's final meeting minutes forced the company to reveal that the FDA might indeed require a completed CVOT before approving the drug, Plaintiffs say, Esperion stock plummeted.

Following a hearing, the district court granted Esperion's motion to dismiss. Relying on our holding in *Kuyat v. BioMimetic Therapeutics, Inc.*, 747 F.3d 435, 440 (6th Cir. 2014), the district court found that Plaintiffs failed to adequately plead a strong inference of scienter because they failed to "identif[y] facts demonstrating that Esperion actually understood the FDA's communications in a way that was different than what was publicly disclosed." The court further held that Esperion's statements were not reckless because they were based upon the company's knowledge that the FDA had never before required a company to complete a CVOT prior to approval of a drug similar to ETC-1002. Last, the district court held that Esperion's statements fell within the Private Securities Litigation Reform Act's (PSLRA) safe harbor provision because they served as the basis for later forward-looking statements by the company. This appeal followed.[1]

II.

We "review the grant of a motion to dismiss under Rule 12(b)(6) *de novo*, construing the record in the light most favorable to the non-moving party and accepting as true all well-pleaded

[1]After the district court granted Esperion's motion to dismiss, Plaintiffs moved to alter or amend the judgment and requested leave to file a second amended complaint, which the district court denied. Because we hold that the district court erred by dismissing Plaintiffs' first amended complaint, we need not address the district court's denial of their post-judgment motion.

allegations in the complaint." *Republic Bank & Tr. Co. v. Bear Stearns & Co., Inc.*, 683 F.3d 239, 246 (6th Cir. 2012) (citations omitted). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to . . . allow[] 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) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

Plaintiffs' securities-fraud claims also implicate the heightened pleading standards of Federal Rule of Civil Procedure 9(b). *Ind. State Dist. Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.* (*Omnicare I*), 583 F.3d 935, 942 (6th Cir. 2009). Accordingly, their complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Id.* at 942-43 (citations and internal quotation marks omitted).

As a final threshold matter, the PSLRA imposes two additional pleading requirements. Plaintiffs' complaint must "'specify each statement alleged to have been misleading' along with 'the reason or reasons why the statement is misleading'" and "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* at 942 (quoting 15 U.S.C. § 78u-4(b)(1), (b)(2)).

III.

A.

To succeed on their claims under § 10(b) of the 1934 Act and SEC Rule 10b-5, Plaintiffs must prove six elements: "(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." *In re Omnicare, Inc. Sec. Litig.* (*Omnicare III*), 769 F.3d 455, 469 (6th Cir. 2014) (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37-38 (2011)). The district court held that Plaintiffs' amended complaint failed to adequately allege a strong inference of scienter. "In the securities-fraud context, scienter includes a knowing and deliberate intent to manipulate,

deceive, or defraud, and recklessness." *Doshi*, 823 F.3d at 1039 (citations and internal quotation marks omitted).

In *Tellabs*, 551 U.S. 308, the Supreme Court set forth a three-part test used by lower courts to determine the sufficiency of a plaintiff's scienter allegations. First, we must "accept all factual allegations in the complaint as true." *Id.* at 322. Second, we "must consider the complaint in its entirety" to determine "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter." *Id.* at 322-23. Third, we "must take into account plausible opposing inferences" and decide whether "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 323-24. We apply this test with reference to nine non-exhaustive factors:

> (1) insider trading at a suspicious time or in an unusual amount; (2) divergence between internal reports and external statements on the same subject; (3) closeness in time of an allegedly fraudulent statement or omission and the later disclosure of inconsistent information; (4) evidence of bribery by a top company official; (5) existence of an ancillary lawsuit charging fraud by a company and the company's quick settlement of that suit; (6) disregard of the most current factual information before making statements; (7) disclosure of accounting information in such a way that its negative implications could only be understood by someone with a high degree of sophistication; (8) the personal interest of certain directors in not informing disinterested directors of an impending sale of stock; and (9) the self-interested motivation of defendants in the form of saving their salaries or jobs.

Omnicare III, 769 F.3d at 473 (quoting *Helwig v. Vencor, Inc.*, 251 F.3d 540, 552 (6th Cir. 2001)).

Plaintiffs' theory of scienter is straightforward. After meeting with the FDA in August, Esperion issued statements saying that the FDA told Esperion that it would not need to complete a CVOT prior to approval in the high-unmet-need patient population, and that the FDA would continue to consider lower LDL-cholesterol levels as a proxy for improved heart health. But after the FDA published its final minutes from the End-of-Phase 2 meeting, Esperion issued statements saying that the FDA might require a completed CVOT before approving ETC-1002, and that there was some doubt regarding whether lower LDL-cholesterol would remain an acceptable proxy. According to Plaintiffs, the only explanation for this discrepancy is that

Esperion's August statements regarding what transpired at the meeting were knowingly or recklessly false. After all, according to administrative guidance, the FDA's minutes are the "official record" of what transpired at the End-of-Phase 2 meeting. U.S. Dep't of Health & Human Servs., *Guidance for Industry*: *Formal Meetings Between the FDA and Sponsors or Applicants* 10, ¶ X (May 2009) (accessible at https://bit.ly/2q3itP6). Therefore, there should have been no substantial difference between the FDA's minutes and Esperion's original account of the meeting.

Esperion offers two possible explanations for the differences between its August and September statements. The company first says that Esperion's September statements were made with "the benefit of further information not available in August"—i.e., the FDA's final minutes. In other words, Esperion suggests that the FDA's minutes did not accurately reflect what transpired at the End-of-Phase 2 meeting. Under this theory, some time after the meeting, the FDA decided to change its positions regarding the necessity of a completed pre-approval CVOT and the viability of LDL-cholesterol as a proxy for cardiovascular risk. Those changes in position were then added to the FDA's meeting minutes, and Esperion was caught unaware.

Second, Esperion suggests that it "might have left the meeting with a different impression than the FDA minutes ultimately reflected." Under this theory, the FDA accurately stated its positions during the meeting, but the company's executives simply misunderstood what the FDA told them. Esperion then repeated those mistaken beliefs—along with significant cautionary language—to its investors in August, and later corrected its statements once the FDA published its minutes.

Neither explanation, however, is more plausible than the knowing or reckless fraud alleged by Plaintiffs. Esperion provides no reason why the FDA would have changed its position following the End-of-Phase 2 meeting. Granted, the FDA has a dispute resolution procedure through which drug sponsors can seek changes to the minutes when there are "significant differences in understanding" between the FDA and the sponsor. *Id.* at 10-11, ¶ XI. This lends credence to Esperion's argument that the FDA's minutes sometimes differ from what actually transpires at a meeting. But here, Esperion did not avail itself of the dispute resolution procedure, even though the FDA's minutes (according to Esperion) represented a material shift

from what the FDA told the company in August. Esperion argues that it could not have gained any advantage from requesting revised minutes, since the FDA could still have required the company to complete a pre-approval CVOT. One advantage readily comes to mind: removing the basis for this suit. Although it is possible that the FDA's minutes differed from what was actually said during the End-of-Phase 2 meeting, this explanation is no more plausible than Plaintiffs' inference that Esperion knowingly and deliberately misrepresented the FDA's statements.

Esperion's suggestion that its executives misapprehended the FDA's position is also unavailing. In a securities-fraud case, an inference of recklessness is sufficient to satisfy a plaintiff's pleading burden on the scienter element. *Doshi*, 823 F.3d at 1039. And in this context, recklessness is defined as "highly unreasonable conduct which is an extreme departure from the standards of ordinary care . . . akin to conscious disregard." *PR Diamonds Inc. v. Chandler*, 364 F.3d 671, 681 (6th Cir. 2004) (citations omitted). If Esperion is conceding that it was told by the FDA that it must complete a CVOT, but then mistakenly told its investors the exact opposite, this supports Plaintiffs' inference of recklessness. This is especially true in light of the high stakes involved. Esperion's success as a company depends entirely upon the success of ETC-1002, its only product, and adding a completed CVOT as a prerequisite to approval makes an already arduous process more costly and lengthy.

Three of the *Helwig* factors weigh in Plaintiffs' favor. First, and most significantly, Plaintiffs have shown divergence between Esperion's internal reports regarding the FDA approval process and its external statements on the same subject. *Helwig*, 251 F.3d at 552. We have described divergence as the "key factor" to a finding of scienter. *City of Monroe Emps. Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 688 (6th Cir. 2005). Plaintiffs allege that the FDA's minutes reflect what actually transpired at the End-of-Phase 2 meeting. Because Esperion executives attended the meeting and presumably understood what was said, Plaintiffs suggest, the company knew internally that the FDA might require a completed pre-approval CVOT, and might not allow the company to use LDL-cholesterol as a surrogate for cardiovascular risk. Yet Esperion's press release, an external statement, "confirmed that LDL-C

remains an acceptable clinical surrogate endpoint," and said that "approval of ETC-1002 in the HeFH and ASCVD patient populations will not require the completion of a [CVOT]."

Esperion balks, arguing that the End-of-Phase 2 meeting and the FDA's minutes do not qualify as "internal reports" for the purpose of the second *Helwig* factor. But this formalistic definition is inconsistent with the way we have understood "internal reports" in the past. In *Bridgestone*, for instance, we viewed the contents of meetings at which senior corporate officers were present as "internal reports." *Id.*

Relatedly, Plaintiffs' allegations also fall under the sixth *Helwig* factor, "disregard of the most current factual information before making statements." *Helwig*, 251 F.3d at 552. Plaintiffs allege, and we must accept as true, that Esperion's August statements to its investors were inconsistent with the most current factual information provided to the company by the FDA.

Last, the "closeness in time" factor also weighs in Plaintiffs' favor, albeit minimally. This factor is viewed as potentially probative of scienter because a "short turnaround ma[kes] it less likely that the corporation did not know that its statement was misleading." *Omnicare III*, 769 F.3d at 484. In *Bridgestone*, we found that a one-week span between an allegedly fraudulent statement and a subsequent inconsistent disclosure was probative of scienter, but we rejected the same inference when confronted with a four-month gap. *Bridgestone*, 399 F.3d at 684, 687-88. Here, the six-week gap between Esperion's August and September statements falls comfortably in between.

None of the other *Helwig* factors apply in this case. Plaintiffs do not allege that Esperion executives engaged in insider trading or bribery, that the company quickly settled an ancillary suit, that the company disclosed accounting information in a confusing manner, or that Esperion directors had a conflict of interest. *See Helwig*, 251 F.3d at 552.

They do claim, though, that Mayleben possessed the "self-interested motivation . . . of saving [his] salar[y] or job[]." *Id.* Under this factor, Plaintiffs argue that Mayleben was motivated to make false statements because his compensation is directly tied to the company's performance. However, general allegations of "an executive's desire to protect his position within a company or increase his compensation" do not comprise a motive for fraud, because

such a desire is shared by all corporate officers. *PR Diamonds*, 364 F.3d at 690 (citations omitted). Rather, "to demonstrate motive, a plaintiff must show concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged." *Id.* Plaintiffs' motive allegations are too general and speculative to support an inference of scienter under the ninth *Helwig* factor.

Nonetheless, "the absence of a motive allegation is not fatal." *Tellabs*, 551 U.S. at 325. Accepting Plaintiffs' factual allegations as true and taking them collectively, as we must do at this juncture, "a reasonable person [would] deem the inference of scienter at least as strong as any opposing inference." *Id.* at 326. Esperion has offered no innocent inference stronger than Plaintiffs' inference that Esperion knowingly or recklessly made material misrepresentations or omissions in its August communications with investors. Such an innocent inference would require us to believe either that the FDA's meeting minutes do not accurately reflect what took place in the meeting, or that Esperion misunderstood what the FDA intended to require. The former is implausible; the latter supports Plaintiffs' allegation of recklessness.

Our decision in *Kuyat* is not to the contrary. There, the plaintiffs alleged that BioMimetic, a company developing a new medical device, misled investors regarding the device's prospects for FDA approval. *Kuyat*, 747 F.3d at 437. The FDA had previously expressed concerns regarding the company's definition of the patient population to be studied, suggesting that it study a broader population. *Id.* at 438. BioMimetic conducted clinical trials, achieved statistically significant results in the company's desired population, and expressed optimism that the FDA would eventually approve its new device. *Id.* at 439. However, the FDA ultimately decided not to approve the device, relying in part upon BioMimetic's failure to show the device's effectiveness in the broader population. *Id.* at 440. A group of investors filed suit, alleging that BioMimetic painted too rosy a picture of the device's prospects of approval, especially in light of the FDA's earlier concerns. *Id.* We held that the plaintiffs failed to adequately plead scienter: "While BioMimetic may have ultimately been mistaken about which population the FDA wanted the company to use . . . there are no facts suggesting the company knew this at the time its representatives spoke." *Id.* at 442. In so holding, we pointed out that the FDA was not definitive in its statements regarding the patient population it expected

BioMimetic to analyze, and we credited the company for its willingness to release the results of a study containing both positive and negative results. *Id.* at 442-43.

Here, unlike *Kuyat*, Plaintiffs allege facts—that the FDA meeting minutes reflect what was said during the End-of-Phase 2 meeting, and that what was said at that meeting was inconsistent with what Esperion told its investors in August—that most assuredly support a strong inference that the company knew its statements were false. At the very least, Plaintiffs' allegations support a strong inference that Esperion recklessly misstated to its investors what the FDA said during the meeting. The district court therefore erred by concluding that Plaintiffs' amended complaint failed to adequately allege scienter.

B.

The PSLRA also contains a limited safe harbor for forward-looking statements. Subject to other limitations that are irrelevant here, in a securities-fraud case, a defendant will not be liable for a material forward-looking statement if either (1) the statement is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement," or (2) "the plaintiff fails to prove that the forward-looking statement . . . was made with actual knowledge . . . that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1)(A)-(B). The statute defines a "forward-looking statement" as, among other things, "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer," and "any statement of the assumptions underlying or relating to" such a statement. *Id.* § 78u-5(i)(1)(B), (D). However, the safe harbor does not extend to "a statement of present or historical fact." *Miller v. Champion Enters. Inc.*, 346 F.3d 660, 678 (6th Cir. 2003).

Esperion argues that its August statements regarding the End-of-Phase 2 meeting fall within this safe harbor, either as forward-looking statements or as assumptions underlying forward-looking statements. Under this theory, Esperion's August statements that the FDA had confirmed that it would not require completion of a CVOT prior to approving ETC-1002 looked toward the prospect of future approval.

Although it is true that Esperion's statements concern an event in the future, that alone does not automatically make them forward-looking statements. In *Julianello v. K-V Pharmaceutical Co.*, 791 F.3d 915, 921 (8th Cir. 2015), our sister circuit supplied a useful test: "The critical inquiry in determining whether a statement is forward-looking is whether its veracity can be determined at the time the statement is made . . . ." If so, then the statement is not forward-looking. Take for instance a man's statement to his friend, "My girlfriend has agreed to marry me." That is not a forward-looking statement. Rather, it is a backward-looking statement concerning a future event. When the man spoke to his friend, it was objectively discernable whether his girlfriend had accepted his proposal—either she had, or she had not.

Similarly, the operative statements here—"[w]e know that [ETC-]1002 will not require a CV outcomes trial to be completed prior to approval in patients with [HeFH] and ASCVD," and the like—are not forward-looking. When Esperion made its statements in August, the company knew what the FDA had told it during the End-of-Phase 2 meeting. Therefore, the truth or falsity of Esperion's statements was discernible at the time they were made.

Esperion might still escape liability, however, if the contested statements were "assumptions underlying or relating to" a forward-looking statement. 15 U.S.C. § 78u-5(i)(1)(D). This is the conclusion reached by the district court, based upon our holding in *Miller*, 346 F.3d at 680-81. There, we held that, consistent with the statutory language, present factual statements that underlie forward-looking statements can fall within the PSLRA's safe harbor. *Id.* Miller concerned, in part, an allegation that the defendant had engaged in fraud by making the following materially false statement:

> As we start the second half of the year, we know that you are as concerned as we are regarding the performance of Champion Enterprises stock compared with the overall market. Housing stocks in general have under[-]performed the markets in 1999, and we are no exception. *Given the continuation of outstanding earnings growth and the successful implementation of our retail strategy*, we challenge ourselves as to what we can do to enhance our stock value in a market dominated by Internet and the Dow Jones Nifty 50 stocks.

Id. at 676 (emphasis added). The plaintiffs in *Miller* alleged that because the word "continuation" referred to the then-present state of affairs, the statement fell outside the PSLRA safe harbor. *Id.* at 676-77. We disagreed, concluding that the "continuation" language,

"although certainly implying some present circumstances, also [was] the basis for the later forward-looking statements" regarding the company's "challenge" to enhance its stock value. *Id.* at 677 (citation and internal quotation marks omitted).

Applying the same standard to this case, Esperion argues that its August statements should be characterized as follows: Esperion was making a forward-looking prediction about the regulatory environment (no completed CVOT required for approval) that was grounded in an underlying historical fact (what the FDA told Esperion at the End-of-Phase 2 meeting). But this argument mischaracterizes the nature of Esperion's statements. Where the language used by the defendant in *Miller* was phrased as an assumption ("*given* the continuation . . ."), here, Esperion's statements were phrased as an observation of a historical fact ("The FDA *confirmed* . . ."). *Miller*'s holding on the "continuation" language was confined to cases of "assumption" language. *Id.* at 677.

A different standard applies where, as here, a defendant makes "mixed statement[s] of present fact and future prediction." *Id.* The *Miller* court held that when a defendant makes mixed statements, and a statement of present or historical fact is specifically challenged as fraudulent, it can be separated from surrounding forward-looking statements that remain within the safe harbor. *Id.* at 678-79. To do so, the statements of fact must be "easily separable from the 'forward-looking statements,'" and the statements of fact must not have been "given merely as an 'assumption underlying' future projections." *Id.* at 679. Put another way, a non-forward-looking statement that can be analyzed discretely from forward-looking statements, and does not function as an express assumption underlying a future projection, is outside the PSLRA safe harbor for forward-looking statements.

Esperion's August statements regarding what the FDA purportedly said during the End-of-Phase 2 meeting—that "[t]he FDA confirmed that LDL-C remains an acceptable clinical surrogate endpoint for the approval of an LDL-C lowering therapy," and that "[w]e know that [ETC-]1002 will not require a CV outcomes trial to be completed prior to approval in . . . those patient populations that the FDA considers to have an appropriate benefit/risk ratio"—are separable statements of fact that are not merely assumptions upon which forward-looking statements were made. The truth or falsity of these statements, and others like them, could have

been ascertained in August when Esperion made the statements. Accordingly, under *Miller*, they fall outside the PSLRA safe harbor, and the district court erred by holding otherwise.

C.

One final issue warrants mention. Plaintiffs' § 20(a) "control person" claim against Mayleben is derivative of their § 10(b) and Rule 10b-5 claims against Esperion. *See Doshi*, 823 F.3d at 1045. Because Plaintiffs adequately pleaded their claims against Esperion, they also adequately pleaded their claims against Mayleben.

REVERSED and REMANDED.