United States Court of Appeals
For the First Circuit

No. 17-1139

WILLIAM KADER, individually and on behalf of all others similarly situated; MORAD GHODOOSHIM; ROGER LAM; LAXMIKANT CHUDASAMA,

Plaintiffs, Appellants,

v.

SAREPTA THERAPEUTICS, INC.; CHRISTOPHER GARABEDIAN; EDWARD M. KAYE, M.D.,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Allison D. Burroughs, U.S. District Judge]

Before

Torruella, Kayatta, and Barron,
Circuit Judges.

Kara M. Wolke, with whom Robert V. Prongay, Jonathan M. Rotter, Glancy Prongay & Murray LLP, Jason M. Leviton and Block & Leviton LLP were on brief, for appellants.

Christopher G. Green, with whom Mark D. Vaughn, Christopher C. Boots, Cassandra A. LaRussa and Ropes & Gray LLP were on brief, for appellees.

April 4, 2018

TORRUELLA, **Circuit Judge**. Plaintiff William Kader and Lead Plaintiffs Morad Ghodooshim, Roger Lam, and Laxmikant Chudasama (collectively, the "Plaintiffs") sought to represent a class of purchasers of securities that Sarepta Therapeutics, Inc. ("Sarepta") issued between April 21, 2014, and October 27, 2014 (the "Class Period"). The Plaintiffs brought securities fraud claims against Sarepta, Sarepta's Chief Executive Officer, Christopher Garabedian ("Garabedian"), and Sarepta's Chief Scientific Officer, Edward M. Kaye ("Kaye") (collectively, the "Defendants"). According to the Plaintiffs, the Defendants knowingly or recklessly misled investors about their target date for submitting an application to the United States Food and Drug Administration ("FDA") for approval of the drug eteplirsen. The district court dismissed the Plaintiffs' First Amended Complaint ("FAC") for failure to state a claim, and then denied them leave to file their Proposed Second Amended Complaint ("PSAC"). We hold that the district court did not err in dismissing the FAC or in denying Plaintiffs leave to file the PSAC.

I. BACKGROUND

A. The FDA's drug-approval process

Before we immerse ourselves in the details of this case, it is useful to give a brief overview of the process through which the FDA reviews and approves drugs. That process begins when the

sponsor of a new drug submits a New Drug Application ("NDA") to the FDA. See 21 U.S.C. § 355(a)-(b); Corban v. Sarepta Therapeutics, Inc., 868 F.3d 31, 34 (1st Cir. 2017) (outlining the FDA's approval process). The FDA then makes the "threshold determination" as to whether the NDA is "sufficiently complete to permit a substantive review." 21 C.F.R. § 314.101(a)(1). "If so, the FDA accepts the application for filing" and then proceeds to "assess[] the merits of the application, deciding whether to approve the drug." Corban, 868 F.3d at 34 (citing 21 C.F.R. § 314.101(a)(1), (f)). "Approval generally requires the application's sponsor to demonstrate the drug's clinical benefit." Id. (citing 21 U.S.C. § 355(d)).

Sponsors of certain drugs may avail themselves of various FDA programs that expedite the review process. These programs aim to facilitate the availability of critical therapies for serious, unmet medical needs. For example, upon a sponsor's showing of adequate preclinical data, the FDA may grant a drug "Fast Track" status. See 21 U.S.C. § 356(b). Among other benefits, the sponsors of "Fast Tracked" drugs may interact more frequently with the FDA to discuss "the drug's development plan and ensure collection of appropriate data needed to support drug approval." U.S. Food & Drug Admin., Fast Track, https://

www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm (last updated Jan. 4, 2018).

Fast Tracked drugs may also be eligible for "Accelerated Approval." Id. The FDA approves drugs in the Accelerated Approval program upon meeting a "surrogate endpoint" or "clinical endpoint" that is "reasonably likely" to predict the drug's clinical benefit. 21 U.S.C. § 356(c). "For example, instead of having to wait to learn if a drug actually extends survival for cancer patients, the FDA may approve a drug based on evidence that the drug shrinks tumors, because tumor shrinkage is considered reasonably likely to predict a real clinical benefit." U.S. Food & Drug Admin., Accelerated Approval, https://www.fda.gov/ForPatients/Approvals/Fast/ucm405447.htm (last updated Jan. 4, 2018). This is particularly useful in the case of drugs intended to treat diseases with longer courses, when measuring the drug's clinical benefit would otherwise require an extended period of time. In such cases, the drug's effect on the surrogate or clinical endpoint may be observable much sooner, allowing the FDA to determine the drug's efficacy at an earlier juncture.

Crucially, once the FDA has approved a drug, the drug's sponsor may begin to market it.

B. The facts underlying this case

Except when we indicate otherwise, we draw the following facts from the FAC.

1.

Duchenne Muscular Dystrophy ("DMD") is a rare genetic neuromuscular disorder that primarily affects boys and young men. As the result of inadequate production of the protein dystrophin, individuals with DMD suffer from progressive muscle loss causing severe disability and premature death. The average life expectancy for someone diagnosed with DMD is 27 years. During the Class Period, no approved disease-modifying therapies for DMD existed. Sarepta, however, was developing drug candidates to treat DMD, including eteplirsen, the drug around which this case revolves. See Corban, 868 F.3d at 34-37 (describing, in the context of a case involving a different class period, Sarepta's development of eteplirsen). During the Class Period, Sarepta's main competitor, Prosensa Therapeutics, Inc., was also developing and seeking approval of a drug candidate to treat DMD. The first company to obtain approval of its drug and succeed in bringing it to market would obtain the "first mover advantage." In pharmaceutical markets, the "first mover" gains a considerable advantage because doctors will quickly prescribe the first available drug of a new type, and are unlikely to switch to

prescribing a different drug of the same type that subsequently becomes available.

The FDA granted eteplirsen Fast Track status in 2007. In 2011, Sarepta began conducting the clinical trials at the center of this case. Study 201, designed as a randomized, double-blind, placebo-controlled study involving 12 participants, sought to assess the effects of "eteplirsen administered intravenously in two different doses over 24 weeks for the treatment of ambulant boys with DMD." The study's participants all underwent muscle biopsies at the study's outset and conclusion to determine if the amount of dystrophin in their muscle tissue had changed over time -- a potential surrogate endpoint by which to assess eteplirsen's efficacy. Study 201's results showed that "treatment with eteplirsen met the primary efficacy endpoint in the study." Following these encouraging results, Sarepta began "Study 202," in which the same participants received varying dosages of eteplirsen for an additional 24 weeks. All of the muscle biopsy dystrophin analysis for both of these studies took place at a single location -- Nationwide Children's Hospital in Columbus, Ohio -- with one doctor overseeing the entirety of the clinical review. Because this analysis requires staining muscle samples with a dye that makes dystrophin visible, and then viewing and analyzing those

samples in slides, the Plaintiffs aver that it is "inherently subjective."

2.

On April 21, 2014 -- the first day of the Class Period -- Sarepta issued a press release discussing the possibility of submitting an NDA for eteplirsen by the year's end. According to the press release, that goal was "based on a guidance letter from the [FDA] that proposed a strategy regarding the submission of an NDA for eteplirsen under a potential Accelerated Approval pathway." The press release quoted the FDA's guidance letter, which explained that "with additional data to support the efficacy and safety of eteplirsen for the treatment of DMD, an NDA should be fileable." The press release also explained that the FDA's letter "outlined examples of additional data and analysis that, if positive, will be important to enhance the acceptability of an NDA filing by addressing areas of ongoing concern in the existing dataset." In addition, the release noted that the FDA had "expressed concerns about methodological problems in the assessments of dystrophin and, 'remain[s] skeptical about the persuasiveness of the (dystrophin) data.'" According to the press release, the FDA had stated that, as a result, it was "uncertain whether the existing dystrophin biomarker data will be persuasive

enough to serve as a surrogate endpoint that is reasonably likely to predict clinical benefit."

That same day, Sarepta held a conference call with investors and analysts to discuss its announcement. Per the guidance letter, Garabedian explained that with "additional data and analysis," Sarepta would be able to "pursue an NDA filing that we will plan to submit by the end of this year, for a potential early approval of eteplirsen sometime in 2015." But, he cautioned, "the guidance letter described the FDA's reservations that the existing data set may not be sufficient to support an NDA filing, or be compelling enough for a favorable review." Garabedian further offered that "[w]e could submit our NDA now on the existing data set, but the FDA has highlighted questions and concerns," for which reason "we are going to be in a much better position if we just wait for some of these additional pieces of data."

Following this announcement, Sarepta shares increased in value by 39.26% on unusually heavy trading volume, closing on April 21, 2014 at $33.98 per share. The following day, Sarepta announced that it planned to offer up to $100 million of its common stock in a public offering. Then, on April 29, it sold 2,650,000 shares of common stock in a public offering at a price of $38.00

per share, resulting in net proceeds of approximately $94.5 million.

On May 7, 2014, Garabedian participated in another conference call with analysts. During that call, he characterized the FDA's guidance letter as communicating to Sarepta, in paraphrased terms:

> [W]e're not telling you you can't submit an NDA tomorrow on the existing data set . . . . But we're telling you that we've raised enough concerns on the existing data set that you would bolster your case for an NDA filing and potentially a favorable review if you allow us to do a more detailed review of your dystrophin methodology [and if you supplement the data set].

In short, Sarepta expressly disclosed that the FDA wanted to do a more detailed review of the study's methodology, and get more data, and that Sarepta's chances of success for an NDA filing would be affected by whether it allowed the FDA to do so. Additionally, during the same month, the FDA also visited Nationwide Children's Hospital -- where Study 201/202 took place -- to review the clinical trial site and protocols in place there.

Then, on July 29, 2014, the FDA requested that "independent pathologists at independent labs" review Sarepta's primary dystrophin endpoint. Sarepta did not disclose this request to the public during the class period. On the same day, the director of the FDA's Center for Drug Evaluation and Research ("CDER") responded via a statement on the White House's website to

a petition urging the FDA to "say YES to Accelerated Approval for safe, effective therapies for children with Duchenne." Her response acknowledged Sarepta's intention of filing an NDA for eteplirsen by the end of 2014.

On August 7, 2014, Garabedian held another conference call with investors and analysts. During that call, he stated that "[a]s a reminder, the FDA indicated in its April guidance that if, after further detailed review, they were to find the currently available dystrophin biomarker data to be adequate, our existing dystrophin data set would have the potential to support accelerated approval." After relaying that the FDA had visited National Children's Hospital, he added that "we continue to work with the FDA to provide greater assurance of the quality and reliability of our dystrophin data in anticipation of a potential NDA filing decision and potential NDA review next year."

However, on October 27, 2014 -- the last day of the Class Period -- Sarepta issued another press release announcing that it had received updated guidance from the FDA regarding its planned NDA submission for eteplirsen. That guidance indicated that the FDA now required Sarepta's NDA to include additional data, including, among other things, "the results from an independent assessment of dystrophin images and the 168-week clinical data from study 202." As a result, the press release explained, Sarepta

would not be able to submit an NDA until mid-2015, as opposed to its prior target of late 2014. On the same day, Sarepta executives also held a conference call with investors and analysts to convey and explain the FDA's concerns. That day, Sarepta shares declined by more than 32%, closing at $15.91 per share, on unusually heavy trading volume.

On October 30, 2014, the FDA issued a public statement addressing "questions the agency has received from DMD patients, their families, and others in the community who are concerned about the timing of the filing of an NDA for eteplirsen." The statement underscored that "[i]n its advice to Sarepta, FDA has consistently stated that it would be necessary to include data in its NDA demonstrating that eteplirsen increases production of the muscle protein dystrophin." The statement also clarified that during the FDA's visit to Nationwide Children's Hospital, "the agency did not find any evidence of fraud at this site, as has been perceived by some." However, the FDA also highlighted its concern "that the methods used to measure dystrophin were not adequately robust to support an NDA submission." Finally, the statement concluded by explaining that the "FDA will continue to work with Sarepta in their efforts to provide the data it considers critical to FDA's ability to review the NDA and reach a decision on approvability."

3.

We add the following facts from the PSAC.

In May 2015, after the Plaintiffs brought this securities fraud suit, see infra Section I.C., Sarepta did file an NDA for eteplirsen. The FDA accepted the NDA for filing on August 25, 2015. While the director of the CDER has the sole authority to approve an NDA, the FDA may call upon advisory committees to provide independent opinions and recommendations during the approval process. The FDA scheduled an advisory committee meeting about the eteplirsen NDA for January 22, 2016. In anticipation of that meeting, the FDA published a briefing document for members of the advisory committee (the "Briefing Document"). That document detailed, among other things, the concerns that the FDA had communicated to Sarepta prior to and during the Class Period.

So too, primarily for purposes of narrative completeness, do we mention the following facts contained neither in the FAC nor the PSAC.

The district court took judicial notice that, on September 19, 2016 -- after briefing on the Plaintiffs' motion for leave to amend had concluded, see infra Section I.C. -- the FDA announced that it had decided to grant accelerated approval to eteplirsen. Moreover, the Plaintiffs ask us to take judicial

notice that this announcement came after an appeal within the FDA to the CDER director's initial decision to grant accelerated approval to eteplirsen. In brief, the Director of CDER's Office of Drug Evaluation brought an appeal challenging that decision on the basis that Study 201/202 was methodologically inadequate. After reviewing the appeal, the FDA Commissioner decided to "defer to [the CDER director's] judgment and authority to make the decision to approve eteplirsen under the accelerated approval pathway."[1] Thus, Sarepta was able to begin marketing eteplirsen.

C. This putative class action

The Plaintiffs filed the FAC on March 20, 2015, alleging two counts: (1) that all of the Defendants violated section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), see 15 U.S.C. § 78j(b), and Securities and Exchange Commission ("SEC") Rule 10b-5, see 17 C.F.R. § 240.10b-5, and (2) that Garabedian and Kaye violated section 20(a) of the Exchange Act. In broad terms, the Plaintiffs alleged that the Defendants, in discussing their intention to file an NDA in 2014, fraudulently misrepresented the FDA's communications to them concerning Sarepta's dystrophin data.

[1] We note that, while we have made reference to these facts, which were not before the district court, they do not end up having the effect of impacting our analysis.

The Defendants moved to dismiss the FAC for failure to state a claim. See Fed. R. Civ. P. 12(b)(6). The district court granted that motion on April 5, 2016. It concluded that the FAC did not allege "sufficient facts to plausibly suggest that Defendants made affirmatively misleading statements, or that they omitted . . . information needed to make their statements not misleading." It also held that the FAC similarly lacked facts supporting an inference of scienter on the part of Sarepta's executives as to the allegedly misleading nature of any of their statements or omissions.

The Plaintiffs then filed a motion for leave to amend the FAC, attaching the PSAC to that motion. The PSAC, unlike the FAC, contained allegations involving the Briefing Document. The Briefing Document, according to the Plaintiffs, demonstrated that the FDA had communicated to Sarepta a "plethora of concerns" about Sarepta's data before and during the Class Period. It also, said the Plaintiffs, illustrated that the Defendants had misrepresented Study 201/202 as "blinded."

On January 6, 2017, the district court denied the Plaintiffs' motion for leave to amend. Specifically, it held that the Plaintiffs had delayed unduly in moving to amend, and that, in any event, the PSAC was futile because it also failed to state a claim. The Plaintiffs now appeal the district court's orders

denying them leave to file the PSAC and dismissing their claims with prejudice.

II. THE DISTRICT COURT PROPERLY DISMISSED THE FAC

We first take up the Plaintiffs' contention that the district court erred in dismissing the FAC for failure to state a claim. Our review of a district court's dismissal under Rule 12(b)(6) is de novo. Schaefer v. Indymac Mortg. Servs., 731 F.3d 98, 103 (1st Cir. 2013). In determining whether the FAC stated a claim upon which relief can be granted, "we accept well-pleaded factual allegations in the complaint as true and view all reasonable inferences in the plaintiffs' favor." ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008).

A. The relevant law

To survive a motion to dismiss under Rule 12(b)(6), a complaint alleging securities fraud under section 10(b) of the Exchange Act and Securities and Exchange Commission Rule 10b–5 must plead six elements: "(1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." Id. at 58. Only the first two elements are at issue here.[2]

[2] While the Plaintiffs also brought claims under section 20(a), those claims are "derivative of 10b-5 claims." Hill v. Gozani, 638 F.3d 40, 53 (1st Cir. 2011). Following a finding that a

The Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4, governs complaints alleging securities fraud and imposes a particularity requirement on pleadings. With regard to misleading representations, the PSLRA requires that complaints "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." Id. § 78u-4(b)(1)(B); see also Aldridge v. A.T. Cross Corp., 284 F.3d 72, 78 (1st Cir. 2002). As for scienter, the PSLRA requires that complaints "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)(A) (emphasis added). To satisfy this "rigorous" requirement, Advest, Inc., 512 F.3d at 58, a plaintiff must "show either that the defendants consciously intended to defraud, or that they acted with a high degree of recklessness," Aldridge, 284 F.3d at 82 (citing Greebel v. FTP Software, Inc., 194 F.3d 185, 198-201 (1st Cir. 1999)). Additionally, the Supreme Court has determined that under the PSLRA, "an inference of scienter must be more than merely plausible or reasonable -- it must be cogent and at least as compelling as

---

company has violated a substantive section of the Exchange Act, section 20(a) imposes joint and several liability on that company's executives unless they "acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t(a).

any opposing inference of nonfraudulent intent." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 314 (2007); see also Advest, Inc., 512 F.3d at 59 ("[W]here there are equally strong inferences for and against scienter, Tellabs now awards the draw to the plaintiff.").

B. Material misrepresentations or omissions

In dismissing the FAC, the district court first held that the complaint failed "to plead any facts plausibly suggesting that Defendants' statements or omissions were materially false or misleading." On appeal, the Plaintiffs argue that the district court was wrong for two reasons: (1) the FDA's October 30, 2014 public statement supports the inference that the Defendants "recklessly misrepresented" their ability to file an NDA by the end of 2014, and (2) after receiving a request for independent review of its dystrophin data in July 2014, and failing to comply with that request, the Defendants misled investors by continuing to represent that a 2014 NDA submission was possible and by failing to disclose that request and the noncompliance with it. We take these arguments in turn.

1.

To begin, we disagree with the Plaintiffs that the FDA's October 30 public statement suggests that the FDA had previously communicated anything to Sarepta (such as, that its data were

inadequate) that would render misleading the Defendants' continued representations that a 2014 NDA submission was possible. That inference would not be reasonable. Contrary to what the Plaintiffs insist, the FDA did not appear to make its October 30 statement with the purpose of correcting any prior misrepresentations by Sarepta. Rather, the statement explicitly purported to "address[] questions the agency has received from DMD patients, their families, and others in the community who are concerned about the timing of the filing of an NDA for eteplirsen."

It is true that the statement highlighted that: (1) "[i]n its advice to Sarepta, FDA has consistently stated that it would be necessary to include data in its NDA demonstrating that eteplirsen increases production of . . . dystrophin"; (2) "the need for additional data and analyses to support the NDA was reinforced by an FDA inspection of the clinical site where dystrophin analyses had been conducted"; and (3) after the site visit, the FDA had "provided Sarepta with detailed recommendations on how to improve these dystrophin analyses, and FDA's most recent advice was consistent with the advice provided after the April 2014 meeting." But none of this supports the inference that the FDA had previously told Sarepta that its data were categorically inadequate. And crucially, the statement also recognized Sarepta's April 2014 announcement of its "plans to submit an NDA for

eteplirsen by the end of 2014," without objecting to it or otherwise characterizing it as misleading or unfounded. So, the FDA's statement cannot serve as the scaffolding for any reasonable inference that the FDA had communicated anything to Sarepta during the Class Period that would make the Defendants' subsequent representations about filing an NDA in 2014 misleading.

2.

The Plaintiffs next turn their focus to the July request for independent review, which was not itself disclosed as such. The Plaintiffs' theory is that once Sarepta received this request, it knew it could not reasonably expect to file an NDA until the requested independent review was completed, and it knew that it was not acceding to the request. As a result, the Plaintiffs say, its continued assertion on the August 7 call that its existing dataset could support accelerated approval was misleading.

To advance this argument, Plaintiffs would have us assume that the July request for independent review was materially different in its potential impact on the likelihood of approval than was the FDA's April request for further review (which had been disclosed to investors). For purposes of our disposition of this appeal, we can make that assumption. In so doing, however, we cannot avoid observing that it is hardly obvious that the July request for independent review was significantly new and that

compliance with it was more mandatory than what had come before. Both before and after the July request, it was the case that the FDA was saying that further review by someone other than Sarepta would affect the chances of approval, which is precisely what Sarepta disclosed.

C. Scienter

The Plaintiffs' pursue two lines of argumentation regarding scienter: (1) that "concealing and avoiding the requests for reassessment recklessly risked misleading investors"; and (2) that Sarepta's significant motive to mislead investors is an indicia of scienter.[3]

1.

Keeping in mind that inferences of scienter under the PSLRA must be "at least as compelling as any opposing inference of nonfraudulent intent," Tellabs, 551 U.S. at 314, we begin with the first of Plaintiffs' arguments. As the district court correctly noted, given that it is the only communication that took place after the FDA made this request, Garabedian's August 7, 2014 phone call with investors is the only communication we need to look at.[4]

[3] The Plaintiffs also argue that Garabedian's evasive response to a question during his May 7 conference call indicated that he was knowingly misleading investors regarding the FDA's July request for independent review. But this cannot be right, because according to the Plaintiffs, the FDA had not yet made that request.

[4] In their reply brief, the Plaintiffs argue that various

In analyzing that call, we also keep in mind our recognition that providing warnings to investors, or otherwise disclosing potential risks, erodes inferences of scienter. See Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 244 (1st Cir. 2015) (holding that defendants' informative disclosures "undercut any inference of scienter"); City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Walters Corp., 632 F.3d 751, 760 (1st Cir. 2011) ("[A]ttempts to provide investors with warnings of risks generally weaken the inference of scienter." (alteration in original) (quoting Ezra Charitable Tr. v. Tyco Int'l, Ltd., 466 F.3d 1, 8 (1st Cir. 2006))).

The substance of what Garabedian communicated during the August 7 phone call severely weakens any inference of scienter. He told investors "[a]s a reminder, the FDA indicated in its April guidance that if, after further detailed review, they were to find the currently available . . . data to be adequate, our existing dystrophin data set would have the potential to support accelerated approval." He further explained that Sarepta was "continu[ing] to work with the FDA to provide greater assurance of the quality

---

statements by the Defendants in April and May of 2014 were misleading in light of the FDA's July request for independent review. But, this argument necessarily fails because, according to the FAC, these phone calls took place before the FDA communicated that request to Sarepta.

and reliability of our dystrophin data." In this manner, Garabedian reminded investors that the FDA was looking for further review, as Sarepta disclosed in April. At the same time, Garabedian gave no assurance that Sarepta would accede to the type of review that the FDA sought. As we have discussed, the difference between those statements and what exactly happened is not obvious, as investors knew that Sarepta's chances would be less if it did not receive a further review. And even accepting the Plaintiffs' position that there was a material difference nonetheless, it was not such that one might reasonably infer scienter from Sarepta's failure to elaborate more fully on any difference between a review by the FDA and a review for the FDA by another lab. In other words, an arguable misrepresentation provides by itself less support for an inference of scienter than does a clear falsehood. See Flannery v. SEC, 810 F.3d 1, 9 (1st Cir. 2015) ("If it is questionable whether a fact is material or its materiality is marginal, that tends to undercut the argument that defendants acted with the requisite intent or extreme recklessness in not disclosing the fact." (quoting City of Dearborn Heights, 632 F.3d at 757)).

We now turn to the Plaintiffs' related argument that Garabedian recklessly risked misleading investors about Sarepta's likelihood of achieving that result by failing to mention that Sarepta was not complying with the FDA's request for independent

review. As we have noted, unlike in its October 2014 guidance, the FDA did not describe compliance with its July 29, 2014 request as a mandatory prerequisite for a successful NDA filing. And as we have previously held, when defendants do not divulge the details of interim "regulatory back-and-forth" with the FDA, that alone cannot support an inference of scienter under the PSLRA when the defendants do provide warnings in broader terms. See Abiomed, Inc., 778 F.3d at 243-44. "There must be some room for give and take between a regulated entity and its regulator." Id. at 244; see also Corban, 868 F.3d at 40 ("The defendants had no legal obligation to loop the public into each detail of every communication with the FDA.").

Additionally, we understand the Plaintiffs' arguments about Sarepta's failure to obtain independent review to assert that Sarepta was avoiding doing so out of concern that its data would not hold up under scrutiny.[5] Thus, the argument that the Defendants needed to disclose that they had not followed this request is a variation on the Plaintiffs' other arguments that the Defendants were not forthcoming about the FDA's concerns about

[5] The Plaintiffs do not, for example, argue that Sarepta avoided complying with this request because it would be costly, or time consuming, or for any other reason unrelated to the risk that independent experts would not be able to confirm the studies' results.

their data's reliability or that they misleadingly claimed that they had strong data. And we note again that Garabedian admitted during the August 7 phone call that the FDA had such concerns about Sarepta's data. So, even if Garabedian made material misrepresentations or omissions regarding the July request for independent review or Sarepta's compliance with it, the inference that he did so with scienter is not sufficiently compelling under Tellabs for purposes of stating a claim for securities fraud.

2.

The Defendants' purported motive to deceive investors similarly fails to make an inference of scienter adequately compelling. Pointing to Sarepta's public offering during the Class Period, the Plaintiffs insist that "[i]n a race for FDA approval and generating no significant revenue, Sarepta was dependent upon offerings to fund its operations; reporting positive news was critical to Sarepta's existence." We have set a high bar for arguments of this sort. Indeed, "catch-all allegations that defendants stood to benefit from wrongdoing" are not enough. Greebel, 194 F.3d at 197 (quoting In re Advanta Corp. Sec. Litig., 180 F.3d 525, 535 (3d Cir. 1999)). Rather, "[w]e require something more than the ever-present desire to improve results, such as allegations that 'the very survival of the company w[as] on the line.'" Corban 868 F.3d at 41 (second alteration in original)

(quoting In re Cabletron Sys. Inc., 311 F.3d 11, 39 (1st Cir. 2002)).

The Plaintiffs do not clear this bar. The FAC is bereft of allegations that Sarepta was financially on the ropes, or that it "would shutter its doors unless it padded earnings by deceiving investors." Corban, 868 F.3d at 42. It may be so that this offering generated revenue that proved useful to Sarepta in its "race for FDA approval," so to secure the "first-mover advantage." Yet, that alone cannot bear the weight of an inference of scienter that is "at least as compelling" as any other. Tellabs, 551 U.S. at 314.

Therefore, because the Plaintiffs did not adequately plead scienter in the FAC, we hold that district court did not err in dismissing the FAC for failure to state a claim.

III. THE DISTRICT COURT PROPERLY DENIED LEAVE TO AMEND

We now turn to the Plaintiffs' arguments that the district court should have granted them leave under Fed. R. Civ. P. 15(a) to file the PSAC. The district court denied leave on the grounds that the Plaintiffs had moved to amend with "undue delay" and because, in any event, the PSAC also failed to state a claim. On appeal, the Plaintiffs urge the opposite: that they did not delay unduly and that the PSAC did state a claim. We assume (without deciding) that the PSAC was not futile, but nonetheless

affirm the district court's denial of leave to amend on undue delay grounds.

Under Fed. R. Civ. P. 15(a)(2), a party may amend a pleading "with the court's leave." The Rule further provides that "[t]he court should freely give leave when justice so requires." Nonetheless, grounds for denying leave include "undue delay, bad faith or dilatory motive . . . repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party . . . [and] futility of amendment." Advest, Inc., 512 F.3d at 55-56 (quoting Forman v. Davis, 371 U.S. 178, 182 (1962)). While "[t]he rule reflects a liberal amendment policy . . . the district court enjoys significant latitude in deciding whether to grant leave to amend." Id. at 55 (citation omitted). And notably, "undue delay in moving to amend, even standing alone," can provide a court with adequate grounds to deny leave. Zullo v. Lombardo (In re Lombardo), 755 F.3d 1, 3 (1st Cir. 2014).

We have previously made the observation that "the longer a plaintiff delays, the more likely [a] motion to amend will be denied." Advest, Inc., 512 F.3d at 57 (citing Steir v. Girl Scouts of the USA, 383 F.3d 7, 12 (1st Cir. 2004)). And we have explicitly condemned a "wait and see" approach to pleading, whereby plaintiffs "having the needed information, deliberately wait in

the wings . . . with another amendment to a complaint should the court hold the first amended complaint was insufficient." Id.

The Plaintiffs filed the FAC on March 20, 2015. The Briefing Document -- the source of the Plaintiffs' new allegations in the PSAC -- became available in January 2016. The district court denied the FAC on April 5, 2016. Three days later, the Plaintiffs moved to file the PSAC.

The PSAC differed from the FAC in two key respects. First, it alleged that the FDA had requested an independent review of Sarepta's dystrophin data in July 2013 (a year earlier than the FAC claimed that this occurred). Second, it alleged that Sarepta had manipulated its dystrophin studies, and that the FDA had communicated concerns to Sarepta that "the blinded nature of the dystrophin study had been improperly broken after initial (blinded) analysis failed to yield positive results." Thus, according to the PSAC, the Defendants "misrepresented that the dystrophin analysis was conducted in a properly blinded and controlled manner, and they misrepresented, omitted, and recklessly ignored the FDA's repeated guidance to seek independent laboratory verification of the dystrophin assessment results."

Highlighting the three-month gap between the FDA's publication of the Briefing Document and the Plaintiffs' motion to amend, the district court reasoned that "[t]he timing of the filing

of the motion to amend suggests that rather than moving promptly for leave to file a new complaint based on new information discovered in January 2016, the Plaintiffs instead waited for the Court's ruling on the Motion to Dismiss before seeking leave to amend." This, it concluded, amounted to "wait and see" pleading, and thus undue delay.

The district court did not abuse its discretion in reaching this conclusion. The Plaintiffs' arguments to the contrary focus on their subjective belief in the strength of the FAC and on minimizing the three months during which they could have moved for leave to amend. We are unmoved by the Plaintiffs' arguments concerning their belief that the FAC adequately stated a claim. Regardless of whether or not they intentionally sandbagged their claims, the fact remains that despite having three months to do so, the Plaintiffs did not move to amend until after the district court dismissed the FAC. And while the Plaintiffs characterize this period of time as "relatively short," we have previously upheld denials of leave to amend on undue delay grounds after a comparable amount of time. See Villanueva v. United States, 662 F.3d 124, 127 (1st Cir. 2011) (affirming a finding of undue delay where the plaintiff moved to amend four months after filing his complaint); Kaye v. New Hampshire, 821 F.2d 31, 34 (1st

Cir. 1987) (per curiam) (finding a three-month delay to be a sufficient basis for denying leave to amend).

We also reject the Plaintiffs' argument that moving to amend post-dismissal is desirable from the perspective of judicial economy. They press that "it would have been neither practical nor economical to move to amend the complaint each time new relevant information was released while dispositive motions were pending in this case . . . especially in the context of [the] dynamic factual developments surrounding the [FDA approval] process." But the Plaintiffs "have it exactly backwards -- their methodology would lead to delays, inefficiencies, and wasted work." Advest, Inc., 512 F.3d at 57. Indeed, the resulting "unnecessary costs and inefficiencies on both the courts and party opponents" is precisely the reason why we refused to sanction a "wait and see" approach to pleading in Advest. Id. It may be so that the Plaintiffs did not move to amend at an earlier juncture because they believed that further information relevant to their claims may have been coming down the pike amid the FDA's consideration of the eteplirsen NDA. But that is not so much an argument against the district court's denial of their motion for leave to amend as it is a suggestion that the Plaintiffs perhaps jumped the gun in filing the FAC. Accordingly, we conclude that

the district court did not abuse its discretion in denying leave to amend on undue delay grounds.[6]

IV. CONCLUSION

The FAC failed to state a claim, and even assuming that the PSAC did not also suffer from that deficiency, the district court did not abuse its discretion in ruling that the Plaintiffs moved to file it with undue delay. Therefore, the district court's judgment is affirmed.

Affirmed.

[6] While both of the PSAC's new claims -- that the FDA had requested independent review in July 2013 and that Sarepta had fraudulently characterized its dystrophin studies as blinded -- derived from the Briefing Document, the PSAC also cited the transcript from the hearing before the district court in Corban, during which a portion of the FDA's July 2013 written guidance to Sarepta (requesting that Sarepta confirm its data independently) was read into the record. Because this hearing took place in August 2015, however, this does not impact our conclusion that the district court did not abuse its discretion in denying leave to amend.