United States Court of Appeals
For the First Circuit

No. 19-2264

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff, Appellee,

v.

DAVID JOHNSTON,

Defendant, Appellant,

AVEO PHARMACEUTICALS, INC.; TUAN HA-NGOC; WILLIAM SLICHENMYER,

Defendants.

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

[Hon. Nathaniel M. Gorton, U.S. District Judge]

Before

Thompson and Kayatta,
Circuit Judges.*

John F. Sylvia, with whom Andrew N. Nathanson, Matthew D. Levitt, Emily Kanstroom Musgrave, Kerime S. Akoglu, and Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., were on brief, for appellant.

* Judge Torruella heard oral argument in this matter and participated in the semble, but he did not participate in the issuance of the panel's opinion in this case. The remaining two panelists therefore issued the opinion pursuant to 28 U.S.C. § 46(d).

John Pagliaro and Martin J. Newhouse on brief for New England Legal Foundation, amicus curiae.

Paul G. Alvarez, Senior Counsel, with whom Robert B. Stebbins, General Counsel, John W. Avery, Deputy Solicitor, and Hope Hall Augustini, Senior Litigation Counsel, were on brief, for appellee.

January 22, 2021

KAYATTA, Circuit Judge. The Food and Drug Administration (FDA) expressed concerns to AVEO Pharmaceuticals about the results of AVEO's clinical trial for tivozanib, a kidney cancer drug candidate. In light of those concerns, the FDA recommended that AVEO conduct another clinical trial. AVEO opted not to disclose that recommendation to the markets until the FDA itself revealed the recommendation eleven months later, at which point AVEO's stock dropped thirty-one percent. In this subsequent civil enforcement action brought by the Securities and Exchange Commission, the principal issue is whether AVEO's CFO, David Johnston, knowingly misled investors by the manner in which he responded to investor inquiries about the substance of AVEO's discussions with the FDA. After an eight-day trial, a jury found against Johnston. On appeal, Johnston argues that he was entitled to judgment as a matter of law because he had no duty to disclose the FDA's recommendation, and because the evidence of scienter was insufficient. Alternatively, Johnston argues that he is entitled to a new trial because the district court improperly instructed the jury on the law of materiality and the duty to disclose. For the following reasons, we find the evidence of fraud and scienter sufficient to support the verdict, and the challenged instructions appropriate.

I.

We begin with a summary of the evidence. Because Johnston challenges the sufficiency of the evidence to support the jury's verdict, we view the evidence in the light most favorable to the verdict and draw any inferences in the verdict's favor. Blomquist v. Horned Dorset Primavera, Inc., 925 F.3d 541, 546 (1st Cir. 2019).

From 2007 to 2013, Johnston served as the Chief Financial Officer of AVEO Pharmaceuticals. As CFO, Johnston was responsible for AVEO's communications to the investing public, including communications about its drug development efforts.

In the spring of 2012, AVEO's financial future largely turned on the success of its lead drug candidate, tivozanib, a drug intended to treat a form of kidney cancer called renal cell carcinoma. The FDA determines whether a drug such as tivozanib may be marketed in the United States. The FDA approval process requires a sponsor such as AVEO to prepare and submit a new drug application (the "NDA"). See 21 U.S.C. § 355(a). Approval generally requires the application's sponsor to demonstrate the drug's clinical benefit. See 21 U.S.C. § 355(d). As announced in its 2011 Form 10-K, AVEO expected to submit an NDA for tivozanib to the FDA during the third quarter of 2012.

In May 2012, AVEO published results from TIVO-1, a Phase 3 clinical trial comparing tivozanib to sorafenib, an

approved kidney cancer treatment. TIVO-1's primary endpoint was to measure progression-free survival (the length of time from when the patient enters the study until the occurrence of either tumor growth or the patient's death). TIVO-1's secondary endpoint was to measure overall survival (the length of time from when the patient starts treatment until the patient dies from any cause). TIVO-1's results showed that tivozanib performed better than sorafenib on progression-free survival but worse than sorafenib on overall survival.

AVEO's representatives met with FDA officials on May 11, 2012, to discuss the prospects of AVEO's anticipated NDA (the "pre-NDA meeting"). During that meeting, the FDA expressed concern about the trend in the available overall survival data for TIVO-1 patients who received tivozanib. The FDA informed AVEO that "[f]urther discussion of these findings will be required at the time of filing and if the application is filed they will be a review issue that could affect approvability." One FDA representative, Dr. Amna Ibrahim, suggested that if AVEO submitted an NDA for tivozanib with the same troubling overall survival data, the FDA might refuse to file it. See 21 C.F.R. § 314.101(a)(1) (providing that an "NDA may be filed" once the "FDA has made a threshold determination that the NDA is sufficiently complete to permit a substantive review").

AVEO argued at the pre-NDA meeting that the overall survival data trend could be explained by the study's one-way crossover design, which gave patients assigned to receive sorafenib the option to take tivozanib if they experienced disease progression but did not allow patients assigned to receive tivozanib to receive sorafenib. But this explanation did not persuade the FDA.

During the pre-NDA meeting, the FDA made two specific recommendations to AVEO. First, the FDA recommended that AVEO conduct a second Phase 3 study for tivozanib ("a second adequately powered randomized trial in a population comparable to that in the US"). Second, the "FDA also recommended that [AVEO] conduct the final analysis of overall survival in the current trial." The meeting minutes jointly prepared with input from both FDA personnel and AVEO representatives memorialized both of these recommendations.

Hours after the pre-NDA meeting, Dr. William Slichenmyer, AVEO's Chief Medical Officer, shared the FDA's feedback on a call with AVEO's executive committee. Slichenmyer repeated "[v]erbatim" the FDA's recommendation at the pre-NDA meeting that AVEO conduct a second Phase 3 study for TIVO. He also informed the committee that "stay[ing] the course" by filing the NDA in the third quarter of 2012 ran a "High Risk of [Refusal to File] or Non-Approval." During the next several weeks,

Slichenmyer also presented the FDA's feedback to the AVEO/Astellas Joint Steering Committee[1] and to AVEO's Board of Directors. Johnston was privy to all of these presentations.

On June 26, 2012, AVEO's Board approved a plan and a budget for the second trial recommended by the FDA. AVEO nevertheless still hoped to obtain approval of its forthcoming NDA before the second trial's end, which would not be for several years. On July 2, 2012, AVEO sent briefing documents to the FDA proposing a post-approval trial (rather than a second pre-approval trial). AVEO also requested a meeting to discuss the FDA's feedback on the proposal (the "Type A meeting").

On August 2, 2012, AVEO filed a Form 8-K and issued a press release that discussed TIVO-1's results. Rather than simply remaining largely silent on the substance of its discussions with the FDA, AVEO issued a "Regulatory Update" disclosing that "[t]he FDA has expressed concern regarding the [overall survival] trend in the TIVO-1 trial and has said that it will review these findings at the time of the NDA filing as well as during the review of the NDA." AVEO told investors that it believed it could "directly address this issue" by "conducting additional analyses to be included in the NDA submission that demonstrate that the [overall

[1] AVEO had entered into a joint venture with Astellas Pharma, Inc., to develop tivozanib and obtain regulatory approval for the drug.

survival] data from TIVO-1 are consistent with improved clinical outcomes in [renal cell carcinoma] patients receiving more than one line of therapy." Although AVEO was "continuing to work toward submitting the NDA by end of the third quarter," it noted there was "a chance that the additional [overall survival] analyses may cause the submission to move into the fourth quarter."

That same day, AVEO held a conference call for investment analysts. In preparation for the call, Johnston and his communications staff created a document scripting responses to anticipated analyst questions. The script gave specific guidance on how to answer questions about whether the FDA had recommended further trials:

> Additional Studies Requested by Agency
> - At this time the Agency has not required an additional study for approval.
> - We are comfortable with our plans to address the [overall survival] concerns and are moving forward with the NDA submission.
>
> IF PUSHED...details on discussions with FDA
> - We wouldn't want to speculate on what the Agency would do in the future.

With Johnston present on the call, Slichenmyer answered analysts' questions in accordance with the script. When Thomas Wei, an investment analyst, asked:

> [W]ould you be able to help us understand, based on your discussions with the agency, let's say that these additional analyses that you're submitting actually are ultimately not sufficient to address their concerns on overall survival. What are the different pathways that you would have going forward to

> get TIVO approved? Is it waiting for the overall survival data to mature, or [are] there . . . other possibilities that maybe the FDA outlined to you as a way to fix this issue?

Slichenmyer responded:

> Yes. So first I want to reaffirm that we believe that the current data package should be sufficient to gain approval. But in the unlikely scenario that we might get into something like you described there[,] I can't speculate on what the agency might be thinking or what additional actions might be necessary. But obviously, it would be tail[or]ed to what, if any, concerns they had.

Wei reasonably understood Slichenmyer's response to mean that "he ha[d] no idea what the FDA might outline as a way to fix the issue."

Salveen Richter, an investment analyst, followed up on Wei's question:

> So, when you met with the FDA and they brought up their concerns, did they kind of point you towards a direction of what studies they wanted you to acquire? And when you commented on these analyses that you're doing, were they comfortable with that or did they kind of push you into a different direction of maybe doing some additional new analyses or additional studies?

Slichenmyer answered:

> Yes. So, we're not going to get into the details of our ongoing discussions with the agency at this point. And really, the key thing about our updating today is because of the potential impact on our NDA submission timeline. And so regarding any future study, I think -- again, I just can't speculate on

> what the agency might want us to do in the future.

Later that day, Richter wrote an investment report stating that "new trials will not be required" for tivozanib, and that report was sent to Johnston on August 3. Another analyst on the call, Adnan Butt, reasonably understood Slichenmyer's answer to Richter's question to mean "[t]hat a discussion of another study has not come up." Following AVEO's August 2 disclosures, AVEO's stock price declined twenty-seven percent.

In a 10-Q filing on August 7, 2012, AVEO repeated the information it had included in its press release regarding the FDA's pre-NDA meeting feedback and revised its planned timeline for filing the NDA from the third quarter to the "second half" of 2012. The August 2012 10-Q also stated that AVEO "cannot be certain as to what type and how many clinical trials the FDA . . . will require us to conduct before we may successfully gain approval to market tivozanib." AVEO noted that "[p]rior to approving a new drug, the FDA generally requires that the efficacy of the drug be demonstrated in two adequate and well-controlled clinical trials." AVEO's subsequent public statements about the FDA's pre-NDA meeting feedback followed the same pattern; when Johnston spoke at investment conferences in August and September, he never mentioned the FDA's recommendation to conduct a second study.

On August 29, 2012, the FDA responded to AVEO's Type A meeting request. The response stated that the FDA had "significant concerns regarding the trial design described in [AVEO's] meeting package" and offered no encouragement that the recommended second study could be done post-marketing. After receiving that feedback, AVEO canceled the Type A meeting.

On September 27, 2012, AVEO submitted an NDA for tivozanib. AVEO's Form 10-Q filing on November 8, 2012, noted the NDA's submission, but it contained a risk disclosure statement much like the one in AVEO's August 2012 Form 10-Q. Later in November, the FDA issued a "Day 74 Letter" notifying AVEO that the NDA submission contained adequate information for the FDA to review the NDA. But the FDA also indicated that the TIVO-1 overall survival data would be a "review issue[]" considered by the Oncologic Drugs Advisory Committee (ODAC).

In January 2013, AVEO conducted a public offering that raised over $53 million. In connection with the offering, the underwriters' legal counsel[2] and AVEO's legal counsel[3] wrote negative assurance letters informing the underwriters that based on their conversations with AVEO's officers and review of AVEO's

[2] Ropes & Gray, LLP, served as counsel to the underwriters.

[3] Wilmer Cutler Pickering Hale and Dorr, LLP, served as counsel to AVEO.

registration statement, pricing disclosure package, and prospectus,[4] no facts that came to their attention caused them to believe that the offering documents omitted "a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading."

On February 26, 2013, the FDA announced in the Federal Register that tivozanib's overall survival data would be reviewed by the ODAC at a meeting on May 2, 2013. The day after the FDA's announcement, Johnston spoke at an investment conference. Adnan Butt, an investment analyst, asked Johnston point-blank: "Have you -- either your partner or the FDA discussed any further trials in kidney cancer so far?" Rather than answering forthrightly, or refusing to answer, Johnston gave the following response:

> We have not had any formal discussions, no. But that brings up an interesting question. There's a whole range of possibilities that might come out of this. On the most positive [end] is that ODAC and the FDA each say, yes, we understand, we believe this is what's happening, very credible, go forth and sell [the] drug. On the other end, they could say, this sounds plausible but we would like to see a confirmatory trial before you start marketing this. That's what we call the bad news scenario. But in between, there's a whole series of things and it's fairly conceivable that they might want a confirmatory trial post-marketing. And it's important for people to understand that that

[4] AVEO's prospectus incorporated by reference several of AVEO's public filings, including the August and November Form 10-Qs.

> would fit in well with our strategy that we already have in our operating plans anyway.

On March 11, 2013, AVEO filed a Form 10-K for 2012, which did not disclose the FDA's recommendation to conduct another study. One week later, AVEO participated in a Type A meeting with the FDA to discuss a second clinical trial for tivozanib. The FDA "encourage[d]" AVEO to "design the trial properly as soon as possible and [to] initiate it independent of the action taken on the current NDA submission," and the FDA added that "[t]he design, conduct, and results of this trial will determine whether this one additional trial will be sufficient for approval purposes." AVEO inquired at the Type A meeting whether the FDA was requiring a second trial before the FDA would approve the tivozanib NDA. The FDA responded that the NDA remained "under review" and that "no final decision ha[d] yet been made on the application."

On April 30, 2013, the FDA released the briefing documents submitted to the ODAC in advance of the May 2 meeting. The briefing documents revealed to the public that the FDA had recommended at the May 2012 pre-NDA meeting that AVEO conduct another trial. After that disclosure, AVEO's stock price dropped thirty-one percent. In May 2013, the ODAC rejected the adequacy of TIVO-1.

II.

The operative complaint in this matter alleged violations of section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5, 17 C.F.R. § 240.10b-5; section 17(a)(1)-(3) of the Securities Act, 15 U.S.C. § 77q(a); and Exchange Act Rule 13a-14, 17 C.F.R. § 240.13a-14.[5] The case went to trial, and, after the SEC rested, Johnston unsuccessfully moved for judgment as a matter of law. The jury returned a verdict in favor of the SEC and against Johnston on all claims. The district court thereafter entered judgment against Johnston, barring him from serving as an officer or director of a public company for two years, ordering disgorgement of $5,677 plus prejudgment interest, imposing a $120,000 civil penalty, and permanently enjoining him from violating securities laws. The district court subsequently denied Johnston's timely renewed motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 50(b) and for a new trial pursuant to Fed. R. Civ. P. 59. Johnston timely appealed.

III.

"A motion for judgment as a matter of law may be granted only if a reasonable person, on the evidence presented, could not reach the conclusion that the jury reached." Visible Sys. Corp. v. Unisys Corp., 551 F.3d 65, 71 (1st Cir. 2008). Johnston

[5] Johnston was not the only defendant sued, but the others settled the claims against them.

challenges the denial of his motion for judgment as a matter of law on two grounds. Johnston first argues that he had no duty to disclose the FDA's recommendation to conduct another clinical trial for tivozanib. Second, he contends that the evidence of scienter was insufficient. We address each argument in turn.

A.

We begin with Johnston's duty-to-disclose argument. The SEC had to prove, among other things, that in connection with the purchase or sale of securities Johnston used or employed "any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b). Pursuant to that statutory authority, the SEC promulgated Rule 10b-5(b), which provides in relevant part that "[i]t shall be unlawful for any person, directly or indirectly, . . . [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). Section 17(a)(2) of the Securities Act prohibits securities sellers from making the same type of statements prohibited by Rule 10b-5(b). 15 U.S.C. § 77q(a)(2). A fact is "material" within the meaning of these provisions if it is substantially likely to be viewed by a reasonable investor as "significantly altering the total mix of information made available." In re Smith & Wesson

Holding Corp. Sec. Litig., 669 F.3d 68, 74 (1st Cir. 2012); Basic Inc. v. Levinson, 485 U.S. 224, 231–32 (1988).

Johnston's argument starts out on solid footing. It is well-settled that the "mere possession of . . . nonpublic information does not create a duty to disclose it." In re Smith & Wesson Holding Corp. Sec. Litig., 669 F.3d at 74 (alteration omitted). This is so even when that nonpublic information is material. Id.[6] And we have observed on several occasions that a company such as AVEO is not, in the ordinary case, "under an affirmative obligation to disclose 'each detail of every communication with the FDA.'" Yan v. ReWalk Robotics Ltd., 973 F.3d 22, 40 (1st Cir. 2020) (quoting In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 40 (1st Cir. 2012)); Corban v. Sarepta Therapeutics, Inc., 868 F.3d 31, 40 (1st Cir. 2017) ("The defendants had no legal obligation to loop the public into each detail of every communication with the FDA."); see also Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 244 (1st Cir. 2015) ("There must be some room for give and take between a regulated entity and its regulator.").

So far, so good. The problem for Johnston is that the SEC finds no need to argue in this case that AVEO's mere knowledge of the FDA's recommendation required AVEO to disclose it. To the

[6] Amicus curiae New England Legal Foundation emphasizes this point in its brief in support of Johnston.

contrary, the SEC assumes, arguendo, that until AVEO spoke as it did on the substance of its communications with the FDA, it was not required to disclose the recommendation. The SEC instead points to the fact that Johnston chose to make statements to analysts and investors about its discussions with the FDA. So the pivotal question is whether those statements were knowingly misleading. Statements can be misleading if they are materially untrue. See 17 C.F.R. § 240.10b-5(b) ("It shall be unlawful . . . [t]o make any untrue statement of material fact . . . ."). They can also be misleading if they are half-truths, painting a materially false picture in what they say because of what they omit. Id. ("It shall be unlawful . . . to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading . . . ."); see generally Corban, 868 F.3d at 40.

When investment analysts inquired about whether the FDA had "outlined" "other possibilities" to address overall survival concerns, such as "additional studies," Johnston knew that there were two readily apparent, non-deceptive answers: "Yes" or "we choose not to answer that question." Likely fearing (or so the jury could have found) that either answer would effectively convey the unhelpful truth, Johnston opted for neither. Instead, he prepped Slichenmyer to respond that he could not "speculate" about "what the agency might be thinking" or "what additional actions

might be necessary," clearly implying that AVEO lacked knowledge short of speculation. And when another investment analyst asked whether the FDA "push[ed] [AVEO] into a different direction of maybe doing . . . additional studies," Slichenmyer again said that he could not "speculate on what the agency might want us to do in the future." The SEC presented evidence that no speculation was necessary on these topics after the FDA recommended in May 2012 that AVEO conduct a second study.

Whether Slichenmyer's foregoing responses as crafted by Johnston and given in his presence could by themselves support the jury's verdict, we need not finally decide. Rather, we point, as the SEC does, to the doubling-down that occurred at the investment conference on February 27, 2013. Johnston was asked, "Have you -- either your partner or the FDA discussed any further trials in kidney cancer so far?" Johnston fielded this question over nine months after AVEO's pre-NDA meeting with the FDA, at which the FDA specifically recommended that AVEO conduct a second trial; about eight months after AVEO proposed to the FDA plans for a second trial; and about six months after the FDA criticized AVEO's proposed design for a second trial. Yet, he responded, "[w]e have not had any formal discussions, no." Offered in the wake of Slichenmyer's scripted deflections, this answer plus Johnston's subsequent description of an additional trial as one outcome in the "range of possibilities that might come out of this" reinforced

the misleading impression that the FDA had not even discussed with AVEO an additional trial during the pre-NDA meeting.

Johnston seeks to insulate his statements from the jury's consideration by pointing to cases posing the issue of whether a company misleads by providing a general acknowledgement of a risk that an adverse event could occur in the future without further explaining its likelihood. See Hill v. Gozani, 638 F.3d 40, 56 (1st Cir. 2011) (disclosing "risk[] associated with . . . reimbursement by third party payors" without explaining that people within the company disagreed about the risk's severity); In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 540–41 (S.D.N.Y 2015) (disclosing that approval depended on "hav[ing] an extremely convincing set of results" without explaining that FDA had indicated need for "a heightened showing of proof . . . to compensate for the less reliable testing methodology used"), aff'd sub nom. Tongue v. Sanofi, 816 F.3d 199, 209 (2d Cir. 2016). These cases explain that identifying the risk of a future adverse event without volunteering an assessment of its likelihood generally will not, by itself, constitute an actionable misrepresentation unless the risk of the event's occurrence "approaches a certainty." Hill, 638 F.3d at 60 (explaining that broad disclosure of risk related to reimbursement was sufficient where the level of risk was unknown); In re Sanofi Sec. Litig., 87 F. Supp. 3d at 540–41 (concluding that company was not required to disclose FDA feedback

where such feedback was not "tantamount to a statement that [the company's drug] could not or would not obtain timely FDA approval"). Here, though, the question is not whether Johnston refused to quantify a generally identified risk of what the future might bring, but rather whether Johnston communicated to investors a false statement about the past: that the FDA had not formally discussed, much less recommended, a second study.

Johnston also points to our decisions in Kader v. Sarepta Therapeutics, Inc., 887 F.3d 48 (1st Cir. 2018), and Corban v. Sarepta Therapeutics, Inc., 868 F.3d 31 (1st Cir. 2017), as supporting his position. We disagree. In Kader, the plaintiffs complained that the defendant had failed to disclose that it was not going to accede to a request by the FDA. See 887 F.3d at 59. But there was no attempt to pretend that the FDA had not made the request, or that the defendant was acceding to it. See id. And, in Corban, we found that the defendant "faithfully represent[ed]" the FDA's position, and that the plaintiff had failed to show how not providing even more information was recklessly or intentionally misleading. 868 F.3d at 40. Neither holding helps a defendant who sketches a false picture of the FDA's feedback on a plainly material point.

In sum, a reasonable jury could find that Johnston used carefully crafted half-truths and distortions to convey a false understanding of the FDA's feedback on the company's clinical trial

and thereby violated his duty to make accurate statements regarding material facts. See Hill, 638 F.3d at 57 ("[E]ven a voluntary disclosure of information that a reasonable investor would consider material must be complete and accurate." (alteration in original) (quoting Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990) (en banc))).

B.

We consider next Johnston's argument that the evidence of scienter was insufficient. Proof of scienter is required to establish violations of section 10(b), Rule 10b-5, and section 17(a)(1), but negligence is sufficient to establish liability under section 17(a)(2) or section 17(a)(3). SEC v. Ficken, 546 F.3d 45, 47 (1st Cir. 2008). Scienter can be established by showing "either that the defendants consciously intended to defraud, or that they acted with a high degree of recklessness." Corban, 868 F.3d at 37 (quoting Aldridge v. A.T. Cross Corp., 284 F.3d 72, 82 (1st Cir. 2002)). A high degree of recklessness "demands 'a highly unreasonable omission,' one that not only involves 'an extreme departure from the standards of ordinary care,' but also 'presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious the actor must have been aware of it.'" Id. (quoting In re Smith & Wesson Holding Corp. Sec. Litig., 669 F.3d at 77).

As this court has observed, a defendant's publication of statements when that defendant "knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter." Aldridge, 284 F.3d at 83 (citing Fla. State Bd. Of Admin. v. Green Tree Fin. Corp., 270 F.3d 645, 655 (8th Cir. 2001)). Johnston's own testimony reflects that he learned of the FDA's recommendation to conduct another study shortly after the pre-NDA meeting. So he knew about the FDA's recommendation when Slichenmyer stuck to Johnston's question-and-answer script during the conference call on August 2, 2012, by stating, when asked whether the FDA had suggested another study, that he "[could not] speculate on what the agency might want us to do in the future." Most importantly, Johnston knew about the FDA's recommendation at the pre-NDA meeting when he denied on February 27, 2013, that AVEO had engaged in "formal discussions" with the FDA about another study. Because that too cleverly crafted denial conflicted with a fact known to him, a reasonable jury considering this evidence could conclude that Johnston "consciously intended to defraud, or that [he] acted with a high degree of recklessness." Id. at 82.

Our decision in Yan v. ReWalk Robotics Ltd., 973 F.3d 22, 40–41 (1st Cir. 2020), is not to the contrary. There, a medical device manufacturer did not disclose an FDA letter warning that noncompliance with a deadline to conduct a postmarket

surveillance study "rendered [its] device misbranded." Id. at 40. The manufacturer had already told investors that failure to comply with the postmarket surveillance study requirement could have the consequences described in the letter. Id. And, importantly, the complaint did not allege that the manufacturer "made any claim concerning its progress with the FDA that was inconsistent with its receipt of the letter." Id.

Johnston makes several other arguments, all of which fail to persuade. First, Johnston repurposes his duty-to-disclose argument as a scienter argument, contending that a reasonable jury could not conclude he acted with scienter because he had no clear obligation to disclose the FDA's recommendation. But even assuming Johnston had no duty to disclose the FDA's pre-NDA meeting feedback in the first instance, he had a duty not to mislead when he described that feedback. It was not, as Johnston puts it, "a close call" whether he breached that duty by denying that AVEO and the FDA had "formal discussions" about another study.

Second, Johnston argues that no reasonable jury could find that he acted with scienter because he and AVEO disclosed the TIVO-1 data, the FDA's overall survival concerns, and their uncertainty about whether a second study would be necessary to obtain NDA approval. But a defendant's disclosure of a subset of unfavorable facts does not prevent that defendant from misleading investors, with scienter, about another known and material

unfavorable fact. Nor does the contention that AVEO would have disclosed the FDA's recommendation in the event the FDA "require[d]" another trial relieve Johnston of the obligation to speak truthfully when discussing whether the FDA had already made a recommendation for such a trial. A reasonable jury would thus be free to reject Johnston's evidence of good faith and conclude that Johnston, with scienter, presented a materially distorted picture of the FDA's feedback.

Third, Johnston argues that no reasonable jury could conclude that he acted with the requisite scienter because he adhered to AVEO's corporate governance protocols. Johnston contends that he could not have made a misleading statement with scienter because legal counsel for AVEO and the underwriters knew of the FDA's recommendation and nevertheless wrote negative assurance letters to the underwriters of AVEO's January 2013 public offering. Johnston also argues that he could not have intended for AVEO's disclosures to mislead because many sophisticated actors working on AVEO's behalf reviewed and approved AVEO's disclosures.

Johnston's claimed adherence to corporate governance protocols, while relevant and perhaps helpful in building a defense based on good faith, does not preclude liability for misrepresentations about the FDA's recommendation to conduct a second study. There was certainly no protocol, after all, saying

that Johnston could make statements designed to cause investors to reasonably believe that which was not true. As for the attorneys' letters, chronology (among other things) defeats the logic of Johnston's attempt to hide behind them. Counsel for AVEO and the underwriters provided the negative assurance letters on January 23, 2013. Johnston made the false and misleading statement that suffices to support the jury's verdict more than a month later. The negative assurance letters simply could not have assessed whether Johnston made a misleading statement of material fact when he said that AVEO and the FDA had not engaged in "formal discussions" about another study.

The negative assurance letters' circumscribed scope also limits their probative value with respect to the statements made prior to January 23, 2013. Both letters made assurances that "the Registration Statement," "the Pricing Disclosure Package," and "the Prospectus," which incorporated AVEO's August and November Form 10-Qs by reference, were truthful and non-misleading based on the information the law firms gathered during their respective due diligence processes. But Johnston does not point to, nor have we found, anything in the record to show that the negative assurance letters made representations about whether AVEO's statements during its various conference calls with or presentations to

investment analysts contained material falsehoods or misleadingly omitted material facts.[7]

Nor does AVEO's review process for disclosures compel the conclusion that the scienter evidence was insufficient. AVEO had no review process vetting Johnston's misleading answers to analysts' questions at investment conferences. A reasonable jury could therefore conclude that Johnston made his misleading statement with scienter on February 27, 2013. This is hardly a case, after all, where the subject of FDA recommendations and a second drug trial came out of the blue. Even where Johnston relied on AVEO's review process before making statements, a reasonable jury could reject Johnston's evidence of good faith and credit the SEC's evidence of scienter.

In summary, because Johnston's calculated statements were inconsistent with known facts, a reasonable jury could conclude that he made those statements at least with a high degree of recklessness. That showing of scienter satisfies the SEC's burden on its section 10(b), Rule 10-b(5), and section 17(a)(1) claims, and it is more than sufficient to satisfy the burden for claims under section 17(a)(2) and (a)(3). Because the SEC

[7] We do not imply that letters of this type from counsel would in other circumstances provide a complete defense. See Markowski v. SEC, 34 F.3d 99, 105 (2d Cir. 1994) (noting that reliance on the advice of counsel "is not a complete defense, but only one factor for consideration").

presented sufficient evidence on each element of its claims, we affirm the denial of Johnston's renewed motion for judgment as a matter of law.[8]

IV.

In the alternative, Johnston seeks a new trial on the basis that the jury instructions contained prejudicial errors. In Johnston's view, a new trial is warranted because the district court (1) failed to describe materiality and the duty to disclose as separate elements and (2) failed to explain that no duty to disclose can arise with respect to interim FDA communications that do not reflect certain outcomes. In considering such preserved arguments, we "afford de novo review to questions as to whether jury instructions capture the essence of the applicable law, while reviewing for abuse of discretion . . . the court's choice of phraseology." Teixeira v. Town of Coventry, 882 F.3d 13, 16 (1st Cir. 2018) (alteration in original) (internal quotation marks omitted) (quoting Ira Green, Inc. v. Mil. Sales & Serv. Co., 775

[8] The SEC also brought a claim against Johnston under Exchange Act Rule 13a-14 for falsely certifying that three AVEO documents -- its Form 10-K filed in March 2013, Form 10-Q filed in November 2012, and Form 10-Q filed in August 2012 -- did not contain any untrue statement of material fact or omit to state a material fact necessary to render the statements made not misleading. See 17 C.F.R. § 240.13a-14. Johnston offers no independent argument for why the verdict against him should be set aside on the SEC's claim under Rule 13a-14. So, in light of his statement on February 27, 2013, Johnston's certification of AVEO's 2012 Form 10-K on March 11, 2013, provides a sufficient basis for the jury's verdict on the SEC's claim under Rule 13a-14.

F.3d 12, 18 (1st Cir. 2014)). We also limit our review to the specific challenges raised by Johnston.

The district court opened with the following:

> With respect to . . . untrue statements of material fact or omissions of material fact, the SEC must prove that Mr. Johnston committed fraud by making one or more statements that were not true when they were made or show that Mr. Johnston failed to disclose a material fact that he had a duty to disclose in order to make the other statements not misleading. For the SEC to prevail, you must unanimously agree on which statement was untrue or which undisclosed fact was misleading and find that the untrue statement or undisclosed fact was material.

See 17 C.F.R. § 240.10b-5(b); 15 U.S.C. § 78j(b); 15 U.S.C. § 77q(a). The court then explained that, "I will now describe the terms 'material' and 'duty to disclose' in a little more detail." First, the court addressed materiality:

> A fact is material if there is a substantial likelihood that a reasonable investor would consider the fact important when making a decision about whether to invest his money in a particular security. In other words, a statement leaves out a material fact if there is a substantial likelihood that a reasonable investor would view the absent fact as significantly altering the total mix of the information available. When information merely creates a possibility that an event affecting a company will later occur, materiality will depend upon a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity.

The court next addressed the duty to disclose:

> You cannot find a Defendant liable if he did not have a duty to disclose the information. Information that is disclosed must be complete and accurate, but not all information that is material and nonpublic must be disclosed. Thus, even if an omitted statement was material, a Defendant cannot be liable for securities fraud if there was no duty to disclose the information at issue. For example, a Defendant does not have a duty to disclose facts that would be interesting to the market, nor must every discussion between a regulated entity and its regulator be disclosed. Rather, a Defendant has a duty to disclose information when it is material and when the fact or facts would need to be revealed so as not to mislead. The fact that a statement is literally accurate does not preclude liability. Some statements, although literally accurate, can become misleading if, in their context and manner of presentation, they would mislead investors.

No reasonable jury listening to these instructions would fail to understand that materiality is a description of the importance of a fact to investors, while the duty to disclose refers to the responsibility to affirmatively reveal some facts. Far from conflating the two elements, the instructions expressly state that "not all information that is material and nonpublic must be disclosed." As for Johnston's second complaint, the instructions also made clear that not every discussion with regulators need be disclosed. A district court certainly has no duty to give an incorrect instruction. Nor is a district court "obliged either to embellish legally correct statements or to cover

every factual permutation." DeCaro v. Hasbro, Inc., 580 F.3d 55, 62 (1st Cir. 2009).

V.

For the foregoing reasons, we affirm the district court's denial of Johnston's motion for judgment as a matter of law and for a new trial.