United States Court of Appeals
For the Second Circuit

August Term 2022

Argued: February 8, 2023
Decided: December 26, 2023

No. 21-2546

IN RE: PHILIP MORRIS INTERNATIONAL INC. SECURITIES LITIGATION

UNION ASSET MANAGEMENT HOLDING AG,

Intervenor-Appellant,

TEAMSTERS LOCAL 710 PENSION FUND,

Movant-Appellant,

v.

PHILIP MORRIS INTERNATIONAL INC., ANDRÉ CALANTZOPOULOS, MARTIN G. KING, JACEK OLCZAK, PATRICK PICAVET, MANUEL C. PEITSCH, FRANK LÜDICKE,

Defendants-Appellees.[*]

Appeal from the United States District Court for the Southern District of New York
No. 18-cv-8049, Ronnie Abrams, *Judge*.

[*] The Clerk of Court is respectfully directed to amend the official case caption as set forth above.

Before: KEARSE, PARKER, and SULLIVAN, *Circuit Judges*.

Union Asset Management Holding AG and Teamsters Local 710 Pension Fund (together, the "Investors") – co-lead plaintiffs in this putative securities-fraud class action against Philip Morris International Inc. ("PMI") and several of its current and former executives (together with PMI, the "Defendants") – appeal from the district court's orders (1) dismissing their first amended complaint, (2) denying reconsideration of such dismissal, and (3) dismissing their second amended complaint. In both complaints, the Investors alleged that Defendants made a series of false and misleading statements about PMI's "IQOS" smoke-free tobacco products, in violation of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5.

On appeal, we are tasked with deciding two matters of first impression in this Circuit. *First*, are a securities-fraud defendant's statements that its scientific studies complied with a methodological standard that is published and internationally recognized, but stated in general and inherently subjective terms, properly analyzed as statements of opinion, rather than fact? *Second*, where a securities-fraud defendant's challenged statements express an interpretation of scientific data that is ultimately endorsed by the Food and Drug Administration, are such statements per se "[]reasonable" (i.e., supported by "meaningful inquiry") as a matter of law under *Tongue v. Sanofi*, 816 F.3d 199, 210, 214 (2d Cir. 2016) (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 188 (2015))? Answering both of these questions in the affirmative, and finding that the record otherwise requires dismissal under existing Circuit precedent, we **AFFIRM** the judgment of the district court.

AFFIRMED.

JEREMY A. LIEBERMAN, Pomerantz LLP, New York, NY (Emma Gilmore, Brian Calandra, Pomerantz LLP, New York, NY; Samuel H. Rudman, David A. Rosenfeld, Robert D. Gerson, Mark T. Millkey, Robbins Geller Rudman & Dowd LLP, Melville, NY; Andrew S. Love, Robbins Geller Rudman & Dowd LLP, San Francisco, CA, *on the brief*), *for Appellants.*

KEVIN M. MCDONOUGH, Latham & Watkins LLP, New York, NY (James E. Brandt, Jooyoung Yeu, Matthew P. Valenti, Latham & Watkins LLP, New York, NY; Kenneth J. Parsigian, Latham & Watkins LLP, Boston, MA; Andrew B. Clubok, Brent T. Murphy, Latham & Watkins LLP, Washington, DC, *on the brief*), *for Appellees.*

RICHARD J. SULLIVAN, *Circuit Judge*:

Union Asset Management Holding AG and Teamsters Local 710 Pension Fund (together, the "Investors") – co-lead plaintiffs in this putative securities-fraud class action against Philip Morris International Inc. ("PMI") and several of its current and former executives (the "Individual Defendants"; together with PMI, the "Defendants") – appeal from the district court's orders (1) dismissing their first amended complaint, (2) denying reconsideration of that dismissal, and (3) dismissing their second amended complaint. In both

complaints, the Investors alleged that between July 26, 2016 and April 18, 2018 (the "Class Period"), Defendants made a series of false and misleading statements about PMI's "IQOS" smoke-free tobacco products, in violation of sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b), 78t(a), and Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5.

On appeal, we are tasked with deciding two matters of first impression in this Circuit. *First*, are a securities-fraud defendant's statements that its scientific studies complied with a methodological standard that is published and internationally recognized, but stated in general and inherently subjective terms, properly analyzed as statements of opinion, rather than fact? *Second*, where a securities-fraud defendant's challenged statements express an interpretation of scientific data that is ultimately endorsed by the Food and Drug Administration (the "FDA"), are such statements per se "[]reasonable" (i.e., supported by "meaningful inquiry") as a matter of law under *Tongue v. Sanofi*, 816 F.3d 199, 210, 214 (2d Cir. 2016) (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 188 (2015))? Answering both of these questions in the affirmative, and finding that the record otherwise requires dismissal under

existing Circuit precedent, we conclude that the district court properly dismissed the Investors' complaint. As a result, we affirm the judgment of the district court.

I. BACKGROUND

A. Facts

PMI is one of the largest cigarette and tobacco manufacturing companies in the world. While PMI's business is limited to consumer markets outside the United States, its stock is publicly traded on the New York Stock Exchange, and its products are marketed and sold in the United States by its former parent corporation. As global cigarette sales have declined, PMI has shifted its focus from cigarettes to the development and commercialization of smoke-free alternatives, known as "reduced-risk products," that are marketed as safer than traditional, combustible cigarettes. To that end, PMI has stated that its "future is in products that have been scientifically demonstrated to be less harmful than cigarettes," J. App'x at 1895 ¶ 37, and that its "ambition is to lead a full-scale effort to ensure that non-combustible products ultimately replace cigarettes to the benefit of adult smokers, society, [PMI,] and [its] shareholders," *id.* at 1885 ¶ 3.

At the center of this litigation is PMI's flagship reduced-risk product, "IQOS." IQOS is an electronic device that *heats* – but does not combust – tobacco

contained in proprietary, single-use cartridges marketed by PMI as "HeatSticks," releasing a flavorful, nicotine-containing aerosol inhaled by the user without fire, ash, or smoke.

PMI first introduced IQOS in Japan, with a limited 2014 launch in the city of Nagoya, followed by a nationwide launch in 2016. IQOS initially performed very well in Japan, capturing a 94% share of the Japanese "heat-not-burn" tobacco market – which nearly tripled in size from 2016 to 2017. Likewise, IQOS's share of the *overall* Japanese tobacco market grew steadily, gaining from 7.1% in 1Q17 to 16.3% in 1Q18.[1] Throughout the Class Period, Japan was the only country where PMI sold IQOS on a nationwide basis.

Around the same time, PMI began the process of seeking FDA authorization to market IQOS in the United States – and, more ambitiously, to market IQOS here as a safer, healthier, and less risky alternative to cigarettes. Between December 2016 and March 2017, PMI applied to the FDA for authorization to market IQOS in the United States either (1) generally (i.e., unaccompanied by any claims about health benefits relative to conventional cigarettes), (2) as a "reduced-exposure"

[1] In this Opinion, we use the shorthand "1Q17" to refer to the first quarter of fiscal year 2017 (and so forth).

tobacco product, or (3) as a "reduced-risk" tobacco product." *See* 21 U.S.C. § 387k(g)(1)–(2) (setting forth standards for FDA authorization of reduced-exposure and reduced-risk claims).[2] In support of these applications, PMI submitted to the FDA a variety of clinical and non-clinical studies that it had commissioned to assess IQOS's toxicological profile and effects on human users. PMI made the results, methodological protocols, and raw data from all such studies available to the public. After submitting its applications, PMI continued to conduct additional studies, the results of which it shared with the FDA in subsequent amendments to its applications.

Meanwhile, PMI and the Individual Defendants expressed optimism about the prospects of both (1) continued sales growth in Japanese markets and (2) FDA approval of PMI's applications. *See infra* Sections III.A (analyzing Defendants' statements regarding scientific studies underlying FDA applications), III.B (analyzing Defendants' statements regarding projected sales in Japan).

[2] A "reduced-exposure" tobacco product refers to a "tobacco product that reduce[s] exposure to harmful chemicals," whereas a "reduced-risk" tobacco product refers to a "product that reduce[s] the risk of tobacco-related diseases." J. App'x at 1934.

On both fronts, however, PMI soon encountered setbacks. In December 2017, while PMI's applications to the FDA remained pending, *Reuters* published an article reporting on a former PMI scientist's criticisms of – and allegations of serious "irregularities" in – the IQOS clinical studies. J. App'x at 2035 ¶ 419. On the day of the *Reuters* article's publication, the price of PMI stock dropped by 3.47%. In January 2018, the Tobacco Products Scientific Advisory Committee (the "TPSAC"), the advisory panel convened by the FDA to conduct a preliminary review of the IQOS studies, issued non-binding recommendations that the FDA grant PMI's application for a reduced-exposure order but deny its application for a reduced-risk order. After the *New York Times* reported on TPSAC's recommendations in an article headlined "F.D.A. Panel Rejects Philip Morris's Claim That Tobacco Stick Is Safer Than Cigarettes," PMI's share price again dropped, this time by 2.81%. *Id.* at 1887–88 ¶¶ 9–10. And then, on April 19, 2018 – the day after the end of the Class Period – PMI announced its 1Q18 earnings, disclosing that while IQOS's share of the Japanese tobacco market was still growing quarter-over-quarter, "HeatSticks sales, which come as a lagging indicator to [IQOS] device sales," *id.* at 1176, were "down 39% from [4Q17] and

well below consensus estimates," *id.* at 1954 ¶ 191. The day of that announcement, the price of PMI stock dropped by 15.58%.

In April 2019, the FDA authorized PMI to market IQOS in the United States, and in July 2020, it further authorized PMI to do so with "reduced-exposure" claims. In the "Scientific Reviews" accompanying these orders, the FDA found PMI's "[s]cientific studies" to have "shown that switching completely from conventional cigarettes to the IQOS system significantly reduces [the] body's exposure to harmful or potentially harmful chemicals." *Id.* at 3004 (emphasis omitted). The FDA further found that, "[a]lthough [PMI] ha[d] not *demonstrated* that [IQOS] . . . will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users," such "dramatic changes in exposure relative to combusted cigarettes are reasonably likely to . . . translate to lower risk of tobacco-related morbidity and mortality." *Id.* at 3007–08. Accordingly, the FDA determined that "a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies." *Id.* at 3008.

B. Procedural History

In September 2018, the City of Westland Police and Fire Retirement System ("Westland"), on behalf of a putative class of all those who purchased PMI stock during the Class Period, filed this action against PMI and three of the Individual Defendants. Westland's original complaint asserted primary claims under section 10(b) of the Exchange Act and SEC Rule 10b-5, as well as control-person-liability claims against three of the Individual Defendants under section 20(a) of the Exchange Act. In February 2019, the district court consolidated this action with three related ones and appointed the Investors as co-lead plaintiffs. A few months later, the Investors filed a consolidated amended class-action complaint, naming all Defendants and otherwise asserting the same legal claims as Westland's original complaint.

In a February 2020 opinion and order, the district court granted Defendants' motion to dismiss the Investors' first amended complaint, finding that the Investors had failed to adequately "allege[] that any of the [Defendants' challenged] statements . . . were false or misleading," Sp. App'x at 21–22, or that "any Defendant acted with the requisite scienter," *id.* at 36. At that time, the district court granted the Investors leave to amend their complaint as to claims

"related to Defendants' [alleged] failure to timely disclose . . . four [2016–2017 non-clinical] studies" of the toxicological makeup of IQOS aerosol, *id.* at 30, while dismissing the remainder of the first amended complaint "with prejudice," *id.* at 42.

The Investors then moved for reconsideration of the district court's February 2020 dismissal order, which the district court denied. After the Investors filed their second amended complaint, Defendants again moved to dismiss. In September 2021, following a full round of briefing and oral argument, the district court granted Defendants' motion – once again finding that the Investors had "failed to adequately plead falsity," *id.* at 85, or "to adequately plead scienter," and once again concluding that each such finding "provide[d] an alternate basis for dismissal of [the Investors'] claims under [s]ection 10(b)" and Rule 10b-5, *id.* at 89. In light of that conclusion, the district court also dismissed the Investors' "derivative" claims under section 20(a). *Id.* at 90. This time, the district court's dismissal was "with prejudice." *Id.*

The Investors timely appealed.

II. STANDARD OF REVIEW

We review de novo the district court's dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), as well as for failure to meet the heightened pleading standards imposed on securities-fraud claims by Rule 9(b) and the Private Securities Litigation Reform Act of 1995 (the "PSLRA"), 15 U.S.C. § 78u-4(b). *See ECA & Loc. 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009). "To survive a motion to dismiss [under Rule 12(b)(6)], a complaint must plead 'enough facts to state a claim to relief that is plausible on its face.'" *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)) (other citation omitted). Pursuant to Rule 9(b), a complaint sounding in fraud also "must state with particularity the circumstances constituting fraud," Fed. R. Civ. P. 9(b), and under the PSRLA, it must "specify each statement alleged to have been misleading[] [and] the reason . . . 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," 15 U.S.C. § 78u-4(b)(1), (2)(A).

III. DISCUSSION

To state a private securities-fraud claim under section 10(b) and Rule 10b-5, a plaintiff must plead "(1) a material misrepresentation or omission by the

defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Stoneridge Inv. Partners, LLC v. Sci.-Atlanta, Inc.*, 552 U.S. 148, 157 (2008); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007) (defining scienter as an "intent to deceive, manipulate, or defraud") (internal quotation marks omitted). The latter four elements are not at issue in this appeal. Here, the Investors alleged that Defendants made false or misleading statements regarding both (1) the results and methodology of scientific studies that PMI conducted in support of its application to the FDA for permission to market IQOS as a "reduced[-]exposure" and/or "modified[-]risk" tobacco product, and (2) the outlook for IQOS's sales performance in Japanese markets. For the reasons explained below, we hold that, with respect to each of the statements challenged by the Investors, the Investors have either failed to plead material falsity or abandoned their challenges on appeal. As a result, we need not reach the merits of the district court's alternative holding on scienter.

A. Challenged Statements Regarding PMI's Scientific Studies of IQOS

1. Statements Regarding the Studies' Methodology

The district court found that many of Defendants' challenged statements about the IQOS studies – characterizing their methodology as "rigorous," "extensive," "thorough," "systematic," "unique in . . . completeness and transparency," "the best science," and "very advanced," and the scientists who performed them as "expert" and "world-class," J. App'x at 1959–2011 ¶¶ 208–09, 212–14, 216–17, 224–25, 228–29, 234, 239, 243, 249, 253, 260, 267–68, 282, 287–88, 291–92, 294, 297–98, 304–05, 313–14, 319, 322, 324, 331, 349, 361, 363, 367 – are inactionable as "mere puffery," Sp. App'x at 23–24. We agree. Because these "vague descriptions" of the studies' methodology "offer only generally optimistic opinions," they "are too general to cause a reasonable investor to rely upon them and therefore are *precisely* the type of puffery that [we] have consistently held to be inactionable." *In re Synchrony Fin. Sec. Litig.*, 988 F.3d 157, 170 (2d Cir. 2021) (emphasis added; internal quotation marks omitted); *see, e.g.*, *ECA*, 553 F.3d at 205–06 (finding puffery where defendant characterized its "risk[-]management processes" as "highly disciplined" and "set[ting] the standard for integrity" (internal quotation marks omitted)); *Lasker v. N.Y. State Elec. & Gas Corp.*, 85 F.3d

55, 58–59 (2d Cir. 1996) (finding puffery where defendant stated that it "would not compromise its financial integrity," was "commit[ed] to creat[ing] earnings opportunities," and that its "business strategies would lead to continued prosperity" (internal quotation marks and alteration omitted)).

The Investors dispute the district court's conclusion, arguing that "these statements were 'determinate, verifiable statements,'" as opposed to puffery. Investors Br. at 40 (quoting *Omnicare*, 575 U.S. at 184) (alteration omitted). But their argument is undermined by the very case they purport to rely on. In *Omnicare*, the Supreme Court gave the following example of "a determinate, verifiable statement": "[t]he TVs we manufacture have the highest resolution available on the market." 575 U.S. at 183–84. "[I]f a competitor had introduced a higher resolution TV," then that would be an objectively "untrue statement of fact"; if no competitor had introduced a higher resolution TV, then it would be a "verifiabl[y]" true statement of fact. *Id.* Here, by contrast, the Investors cannot point to any objective, black-and-white standard by which to verify whether PMI's scientific studies were in fact "rigorous," "very advanced," or "the best science." The district court was therefore justified in concluding that the statements about the IQOS studies were not actionable.

In a similar vein, the district court found that another broad swath of challenged statements – namely, Defendants' various representations that PMI's IQOS studies were "conducted according to Good Clinical Practice ('GCP')," J. App'x at 1902 ¶ 54; *see id.* at 1962–2011 ¶¶ 218, 224, 226, 269, 287, 291, 300, 306, 308, 310–11, 361 – "constitute[d] inactionable statements of opinion," Sp. App'x at 28. On appeal, the Investors argue that, since Defendants "did not couch those statements with words such as 'we think' or 'we believe,'" they "were statements of fact, not opinion." Investors Br. at 42 (citing *Omnicare*, 575 U.S. at 183).

Once again, however, the Investors' reliance on *Omnicare* is misplaced. In the passage cited by the Investors, the Supreme Court was rejecting a securities-fraud plaintiff's argument that a "statement that 'we believe we are following the law' conveys that 'we in fact are following the law.'" *Omnicare*, 575 U.S. at 183. Considered in that context, the Court's point was that language like "we believe" or "we think" is *sufficient* – not *necessary* – to render a statement one of opinion rather than fact. Indeed, the Court went on to clarify that where a statement expresses an "inherently subjective . . . assessment," that is *also* sufficient to render it one "of pure opinion." *Id.* at 186. Thus, the materiality of "Defendants' . . . statements about their compliance with GCP" turns on whether

they were "inherently subjective" (as Defendants argue), Defendants Br. at 38, or ones whose objective, "fact[ual]" truth or falsity could be ascertained "with certainty" (as the Investors argue), Investors Br. at 42. *See, e.g.*, *Fait v. Regions Fin. Corp.*, 655 F.3d 105, 110, 113 (2d Cir. 2011) (contrasting "matters of objective fact" with "inherently subjective" judgments that cannot be measured under an "objective standard"), *abrogated on other grounds by Omnicare*, 575 U.S. 175, *as recognized in Abramson v. Newlink Genetics Corp.*, 965 F.3d 165 (2d Cir. 2020).

Defendants have the better of this argument. The Investors assert that "'GCP' is a technical term [that] investors consider to be a verifiable fact that can be relied upon." Investors Br. at 27. Likewise, they repeatedly refer to PMI's putative "GCP *violations*," Investors Br. at 2, 5, 7–9, 28, 43, 47–48, 65 (emphasis added), ostensibly suggesting that GCP is a set of hard-and-fast *rules*, of which violations could be established as a "matter[] of objective fact," *Fait*, 655 F.3d at 110; *see also Omnicare*, 575 U.S. at 183 ("[A corporation]'s statement that . . . 'we . . . are following the law' . . . is materially false, no matter what the [corporation] thinks, if instead it is violating an anti-kickback statute." (other internal quotation marks omitted)). Defendants, on the other hand, analogize GCP to "generally accepted auditing standards" whose "general and often

inherently subjective nature" is such that an "auditor's statement of compliance with generally accepted auditing standards 'cannot properly be characterized as a statement of fact.'" Defendants Br. at 38 (quoting *In re Lehman Bros. Sec. & ERISA Litig.*, 131 F. Supp. 3d 241, 250 n.44 (S.D.N.Y. 2015)).

Defendants' view is confirmed by the Investors' own complaint, which defines the "requirements" of GCP as follows: "clinical trials should be scientifically sound"; "individual[s] involved in conducting a trial . . . should be qualified by education, training, and experience"; and "[t]he investigator should have adequate resources to properly conduct the trial[] [and] should be thoroughly familiar with the appropriate use of the investigational product(s)." J. App'x at 1904 ¶ 58 (quoting Int'l Council for Harmonisation of Tech. Requirements for Pharms. for Hum. Use, Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) 9 (2016), *available at* https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf) (other citations, internal quotation marks, and alterations omitted). Whether a clinical trial is "sound," whether a researcher is "qualified," and whether resources are "adequate," *id.*, are all questions that require "inherently subjective . . . assessment[s]," *Omnicare*, 575 U.S. at 186, and thus do not lend themselves to

resolution as "matters of objective fact," *Fait*, 655 F.3d at 110. So too, then, is the ultimate question of whether PMI's clinical trials of IQOS complied with or violated GCP.

As a practical matter, we see no meaningful daylight between a statement that "we complied with Good Clinical Practices" and a statement that "our clinical practices are good" – the latter of which would *obviously* be a statement of opinion. Indeed, the point is well illustrated by the factual record of this case. Whereas the Investors rely heavily on a "former PMI scientist['s]" statements "*confirming* GCP violations" for a 2017 *Reuters* investigative report, Investors Br. at 8 (emphasis added), the FDA identified *no* GCP violations in its own extensive Scientific Review of PMI's IQOS studies – which it conducted *after* being provided with the full findings of the 2017 *Reuters* investigation. As a result, Defendants' statements regarding GCP compliance are necessarily statements of opinion.

The Investors nevertheless press on to argue that, even if Defendants' "repeated statements about . . . compliance with GCP" *were* properly classified by the district court as "statements of . . . opinion," they nevertheless "are actionable because they omitted facts that rendered [them] misleading." Investors Br. at 42–43 (citing *Abramson*, 965 F.3d at 176). But this alternative argument fails for

substantially the same reasons as the Investors' primary argument regarding the GCP statements.

The Investors point to putative "GCP violations" as the "facts" that "[D]efendants knew of," but "omitted" from, their "statements about . . . compliance with GCP." Investors Br. at 43. But as explained above, the Investors' view that "the [IQOS clinical] trials were marred by . . . violations of GCP," *id.* at 40, is no less an "inherently subjective . . . assessment" – no less a "statement of pure opinion," *Omnicare*, 575 U.S. at 186 – than the Defendants' (and FDA's) view that the trials *were* GCP-compliant. And while "a statement of opinion" is actionable "when [it] implies . . . the absence of contrary *facts[]* and the speaker knows or reasonably should know of different material *facts* that were omitted," *Abramson*, 965 F.3d at 175 (emphasis added), we have never held that a statement of opinion can be rendered actionable by the speaker's failure to mention the *possibility* of contrary *opinions*. Such a holding would violate the fundamental principle that the securities laws do not "require[]" the "[p]eople in charge of an enterprise . . . to take a gloomy, fearful[,] or defeatist view of the future," and instead allow them "to be confident about their stewardship and the prospects of the business that they manage." *Rombach v. Chang*, 355 F.3d 164, 174

(2d Cir. 2004) (internal quotation marks omitted). We reject the Investors' invitation to violate that principle here.

2. Statements Regarding the Studies' Results

We next turn to the challenged statements regarding the *results* of PMI's IQOS studies, which fall into two broad categories. The first comprises statements about the long-term health effects that could be inferred from the totality of the evidence collected in PMI's short-term clinical trials and non-clinical toxicology studies. The second comprises statements regarding unfavorable findings from PMI's non-clinical toxicology studies of the aerosol produced by IQOS devices. We address each in turn.

Exemplary of the first category is the following statement made by PMI's Chief Scientific Officer for Reduced-Risk Products, Manuel Peitsch, on a September 2016 call with investors and analysts:

> [T]he scientific research conducted across a range of studies demonstrates that IQOS has a wide array of benefits compared to smoking cigarettes. We have focused on the health effects of the product and its potential to reduce risk . . . . [T]he totality of the evidence generated to[ ]date supports our conclusion that IQOS has the potential to reduce the risk of smoking-related diseases in adult smokers who switch to it completely.

J. App'x at 1998 ¶ 328 (emphasis omitted); *see also id.* at 2003 ¶ 341 ("Studies conducted to date clearly indicate that IQOS is likely to present less risk of harm compared to smoking." (alteration and emphasis omitted)), 2004 ¶ 343 ("The study . . . clearly indicates areas of significant risk reduction[,] which we are currently confirming through a longer[-]term study." (emphasis omitted)), 2009–10 ¶ 359 ("Findings to date show that switching completely to IQOS is likely to present less risk of harm than continued smoking . . . . These results give us confidence that switching fully to IQOS is likely to present less risk of harm than continuing to smoke." (emphasis omitted; capitalization standardized)). Principally, the Investors argue that these statements were revealed to be false when the TPSAC found that "the evidence is not sufficient to demonstrate substantiation of either of the claims about reduced risk of tobacco-related disease or harm." *Id.* at 2973.

We have "rejected" the proposition that a mere "dispute about the proper interpretation of data" can form "a basis for liability" under section 10(b) and Rule 10b-5. *Tongue*, 816 F.3d at 214. That is, where "[plaintiffs] (and others) . . . take issue with" a defendant's "view regarding . . . the results [of the defendant's scientific studies]," but the "defendant's competing analysis or interpretation of data is itself *reasonable*, there is no false statement." *Kleinman v. Elan Corp., plc*, 706

F.3d 145, 154 (2d Cir. 2013) (emphasis added). We also have previously suggested in dicta – and now hold – that where "the FDA eventually accept[s]" a "[d]efendant['s] interpretation of the data," that interpretation is per se "[]reasonable" as a matter of law. *Tongue*, 816 F.3d at 214. Moreover, "[d]efendants' statements about the [implications of their data] cannot be misleading merely because [a regulatory body] disagreed with the [defendants'] conclusion"; rather, "so long as [the defendants] conducted a 'meaningful' inquiry and in fact held th[e] view" they expressed, their statements will not be deemed to "mislead in a manner that is actionable." *Id.* (quoting *Omnicare*, 575 U.S. at 188–90).

Applying the framework we set out in *Tongue* and *Kleinman*, the district court found that "the FDA essentially endorsed Defendants' statements about [their] scientific data," Sp. App'x at 79, in its June 2020 Scientific Review of the IQOS studies and its July 2020 order granting PMI's application to market IQOS as a "reduced-exposure" product, *see* J. App'x at 2221 (FDA stating that PMI's "[s]cientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces [the] body's exposure to harmful or potentially harmful chemicals"). The district court further found that,

in any event, "Defendants' statements appear[ed] to be supported by their 'meaningful inquiry' into the health benefits of IQOS." Sp. App'x at 27 (quoting *Tongue*, 816 F.3d at 214) (capitalization standardized).

On appeal, the Investors argue that the district court's reliance on the FDA's Scientific Review and reduced-exposure order was both factually and legally erroneous. As to the facts, the Investors argue that "even if [PMI's] clinical trials showed a . . . *reduction in exposure* to harmful chemicals in IQOS compared to cigarette smoke," that "is not directly linked to a *reduction in risk of harm*." Investors Br. at 50 (capitalization standardized); *see also id.* at 45 ("[D]efendants repeatedly misrepresented . . . the data by falsely equating a finding of *lower exposure* to some chemicals with *lower risk of harm* . . . ."). But this argument misconstrues what both the FDA and the Defendants actually said about the correlation between reduced exposure and reduced risk.

The FDA concluded that PMI's studies "ha[d] shown that switching completely from conventional cigarettes to the IQOS system significantly reduces [the] body's exposure to harmful or potentially harmful chemicals" – and that "such dramatic changes in exposure relative to combusted cigarettes are *reasonably likely to . . . translate to lower risk*." J. App'x at 2221, 3008 (emphasis added). To

be sure, the FDA found that PMI's short-term studies (i.e., the "scientific evidence . . . available without conducting long-term epidemiological studies") had not conclusively "*demonstrated* that [IQOS] . . . will significantly reduce harm and the risk of tobacco-related disease." *Id.* at 2974, 3007. But the FDA nevertheless concluded that PMI "*ha[d] demonstrated* that . . . measurable and substantial reduction in morbidity or mortality among individual tobacco users is *reasonably likely in subsequent studies*." *Id.* at 2975 (second emphasis added); *see also id.* at 3008 (FDA reaffirming that conclusion).

These conclusions by the FDA essentially mirror Defendants' carefully measured statements about the IQOS studies' implications for long-term health outcomes. *See, e.g., id.* at 1997–98 ¶ 328 ("[T]he evidence generated to[ ]date supports our conclusion that IQOS has the *potential* to reduce the risk of smoking-related diseases . . . . " (other emphasis omitted)), 2003 ¶ 341 ("Studies conducted to date clearly indicate that IQOS is *likely* to present less risk of harm . . . ." (alteration and other emphasis omitted)), 2004 ¶ 343 ("The study . . . clearly indicates areas of significant risk reduction[,] *which we are currently confirming through a longer[-]term study*." (other emphasis omitted)). Since "the FDA eventually accepted" the Defendants' "interpretation of the data" from the

IQOS studies, any allegation "that Defendants' interpretation of the data was irrational or unreasonable . . . would have little merit." *Tongue*, 816 F.3d at 214.

Unable to refute the fact that "the FDA ultimately endorsed PMI's view of the data," the Investors argue that it was legally "erroneous[]" for the district court to rely on the FDA's 2020 findings in assessing "the contemporaneous falsity of the [D]efendants' statements and omissions made years earlier." Investors Br. at 51. Such reliance, they urge, violated the principle that "the securities[-]laws approach matters from an ex ante perspective: just as a statement true when made does not become fraudulent because things unexpectedly go wrong, so a statement materially false when made does not become acceptable because it happens to come true." *Id.* (quoting *Pommer v. Medtest Corp.*, 961 F.2d 620, 623 (7th Cir. 1992)) (alteration omitted). But *Pommer* is clearly inapposite. There, a corporate executive had "told [investors] that [his company] *had* a patent" when the company did *not*, in fact, have such a patent, and the Seventh Circuit held that "it does not matter that [the company] obtained the patent two years later." *Pommer*, 961 F.2d at 623. *Pommer*, then, stands for the proposition that if a statement of objective fact *is objectively false when made*, it is irrelevant that the statement *would have been objectively true* if made on some later date.

Here, by contrast, we are dealing not with statements of fact, but with statements "about the proper interpretation of data." *Tongue*, 816 F.3d at 214. Accordingly, the question before us is not whether Defendants' statements were factually false when made, but whether they expressed an "interpretation of the data" that was objectively "irrational or unreasonable" when they were made. *Id.* And much as the Investors use the later-published *Reuters* article to suggest that Defendants' statements about their interpretation of the data were contemporaneously *unreasonable*, the district court simply used the later-issued FDA orders and Scientific Reports to confirm that they were contemporaneously *reasonable*. Under our precedents, that was undoubtedly proper. *See id.* (reasoning that "an[y] allegation" that "[d]efendants' interpretation of the data was irrational or unreasonable . . . would have little merit . . . as the FDA *eventually* accepted [it]" (emphasis added)).

Indeed, as noted above, the FDA's ultimate endorsement of Defendants' interpretation of the clinical-studies data *conclusively* establishes that Defendants' statements were reasonable, and therefore not actionable, under *Tongue* and *Omnicare*. After all, the Investors' theory of materiality is that PMI's "future depended on" securing "FDA[] approval not only to sell IQOS, but also to market

it as . . . a product significantly safer than conventional cigarettes," and that the material effect of Defendants' challenged statements was thus "to assure . . . wary investors . . . . that PMI's clinical trials" could persuade the FDA to grant such approval. Investors Br. at 2, 6 (internal quotation marks omitted; capitalization standardized). Within that context, all that matters is that the FDA found PMI's interpretation of its data to be reasonable. It is immaterial that contrary views were held – and even published – by individuals and entities with no say over the regulatory process that PMI's "future depended on." *Id.* at 6 (internal quotation marks omitted). At bottom, then, the district court properly found that "Defendants' statements about the results of [PMI's] clinical studies were not [affirmatively] misleading." Sp. App'x at 27.

The Investors *also* argue that even if these statements were not affirmatively misleading, they were misleading by omission. Namely, they contend that "a reasonable investor would understand [these] statements to mean that PMI had disclosed all material information in its possession relevant to determining whether IQOS had a reduced risk of harm compared to cigarettes," when in fact, PMI "had not [yet] disclosed [four] studies revealing that IQOS contained significant increases of more than a dozen harmful chemicals compared to

cigarettes." Investors Br. at 46 (capitalization standardized). But an opinion statement about the "interpretation of . . . data" is "not misleading simply because the [speaker] 'knows, but fails to disclose, some fact cutting the other way.'" *Tongue*, 816 F.3d at 210, 214 (quoting *Omnicare*, 575 U.S. at 189). Instead, such a statement is "misleading and actionable" only "[w]hen [the] omitted contrary facts *substantially undermine* the conclusion [that] a *reasonable investor* would reach from [the] statement." *Abramson*, 965 F.3d at 177 (emphasis added). That is not the case here.

Once again, the Investors' own theory of materiality is that these statements conveyed to investors that the findings of PMI's scientific studies were sufficient to persuade the FDA to allow PMI to sell IQOS in the United States and market it as a safer alternative to conventional cigarettes. *After* reviewing the results of the four so-called "aerosol studies" – discussed in greater detail below, in the context of affirmative statements that Defendants made about them – the FDA did just that. It is therefore clear that Defendants' broadly optimistic statements about the prospects for FDA authorization were not "substantially undermine[d]" by their failure to disclose certain unfavorable data points from the aerosol studies. *Id.*

Next, we turn to the challenged *affirmative* statements that Defendants made about the aerosol studies – non-clinical toxicology studies of all chemical compounds present in the aerosol produced by IQOS devices – that PMI conducted in 2016 and 2017. On appeal, the Investors focus on two statements that PMI made about these studies in its May 2017 "Scientific Update for Smoke-Free Products."

First, the Investors challenge PMI's statement that "the harmful chemicals found in tobacco smoke are reduced on average by 90–95%" in IQOS aerosol. J. App'x at 2005 ¶ 347 (emphasis omitted). This statement, however, is verifiably true as a matter of objective fact. In its April 2019 Scientific Review, the FDA found that on average, the concentration of FDA-recognized harmful or potentially harmful constituents ("HPHCs") in IQOS aerosol was reduced by 92.825% compared to reference cigarette smoke, and by 90.8625% even after normalizing HPHC concentrations relative to nicotine yield. This sort of "true statement[,]" of course, is not "actionable." *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)), *aff'd*, 604 F. App'x 62 (2d Cir. 2015).

Second, the Investors take issue with PMI's statement that "our . . . results from the non-clinical assessment[s]" of "the [IQOS] aerosol" – "compared with cigarette smoke" – "reveal *reduced toxicity* and *no new hazards*." J. App'x at 2006 ¶ 351 (other emphasis omitted). For starters, the "reduced-toxicity" representation is not actionable since it too was a true statement of fact. Indeed, the FDA found that overall "[]toxicity [levels] for the [IQOS aerosol] [were] reduced by ~95% (per stick)[,] and ~90% when normalized to nicotine content[,] . . . compared to [reference cigarette smoke]." *Id.* at 2882.

PMI's statement that the "results" of the aerosol studies "reveal . . . no new hazards," *id.* at 2006 ¶ 351 (emphasis omitted), presents a closer question. The Investors allege that this statement is false and misleading because "the results of the [aerosol] [s]tudies . . . identified *[eighty] compounds* to be of 'higher concentration or new' in IQOS when compared to a conventional cigarette, of which '[four] compounds are classified mutagens/carcinogens' and '[eight] compounds present potential genotoxic concerns.'" Investors Br. at 52 (quoting J. App'x at 1919 ¶ 98) (capitalization standardized).

But once again, the relevant inquiry turns on the reasonableness of PMI's interpretation of the data from the aerosol studies and its representation that the

data indicated no *hazards* that were *new*. *See Hazard*, Merriam-Webster, https://www.merriam-webster.com/dictionary/hazard (last visited September 12, 2023) (defining "hazard" as a "source of danger" and synonymous to "risk"); *New*, Merriam-Webster, https://www.merriam-webster.com/dictionary/new (last visited September 12, 2023) (defining "new" to mean "having recently come into existence" or "being other than the former or old"). PMI's interpretation – namely, that the aerosol studies revealed no risks or sources of danger that were not previously in existence – was reasonable in light of the FDA's determination that the "IQOS aerosols contain[ed] considerably lower levels of potential carcinogens and toxic chemicals that can harm the respiratory or reproductive systems," J. App'x at 2221, and "fewer toxic chemicals than cigarette smoke," *id.* at 2226. Notwithstanding the Investors' contrary conclusions about the aerosol-studies data, "a dispute about the proper interpretation of data" cannot render PMI's otherwise reasonable interpretation false and misleading. *Tongue*, 816 F.3d at 214; *see also Kleinman*, 706 F.3d at 154 (explaining that "there is no false statement" under our securities laws so long as a defendant's "interpretation of data is itself reasonable").

The Investors nevertheless pivot to a different interpretation of PMI's statement, insisting that "no new hazards" must mean no increases in the concentrations of hazardous chemical compounds that were already present in cigarette smoke to begin with. According to the Investors, *any* increase in the level of a previously present hazardous compound would make PMI's representation of "no new hazards" a false statement. But clearly, that is not what "a reasonable investor would have understood" PMI's statement to mean. *IWA Forest Indus. Pension Plan v. Textron Inc.*, 14 F.4th 141, 146 (2d Cir. 2021). In short, the Investors must do more than allege an abstract percentage-point increase in certain chemical-compound concentrations in the IQOS aerosol as compared to cigarette smoke. They must instead allege that such increases were actually *hazardous* – i.e., that they posed greater risk or were sources of danger. Properly framed, the Investors' newfound theory of falsity fails for the simple reason that the FDA ultimately concluded that "[a]lthough some chemicals of potential concern (not on FDA's HPHC list) may be higher in IQOS, the increase in these constituents does not impact the conclusion that the substantial reductions in HPHCs and findings from the toxicological evidence are reasonably likely to

translate to lower risk of tobacco-related morbidity and mortality." J. App'x at 2976.

In the alternative, the Investors argue that the "no-new-hazards" statement meant that the aerosol studies did not reveal the existence of *any* hazardous chemical compounds *not* previously present in cigarette smoke. But, as a "determinate, verifiable" issue of fact, *Omnicare*, 575 U.S. at 184, the hazardous chemical compounds that the Investors identified from the results of the aerosol studies – that is, the four compounds classified as mutagens/carcinogens and the eight compounds classified as potentially genotoxic – are among those already present in reference cigarette smoke, *see* J. App'x at 1920–22 ¶¶ 101, 103. Thus, they cannot be *new* "source[s] of danger." *Hazard*, Merriam-Webster. For all of these reasons, we find no falsity in PMI's statement that the "results from the non-clinical assessment[s]" of "the [IQOS] aerosol reveal . . . no new hazards," "compared with cigarette smoke." *Id.* at 2006 ¶ 351 (emphasis omitted).

B. Challenged Statements Regarding Projections for IQOS Sales in Japan

We now turn to Defendants' statements regarding their projections for IQOS's Fiscal Year 2018 sales performance in Japanese markets. The Investors claim that (1) André Calantzopoulos, PMI's then-CEO, affirmatively

misrepresented PMI's internal projections during a February 2018 earnings call with investors; and (2) PMI materially omitted, from the SEC 10-K and 10-Q Forms it filed throughout the Class Period, disclosures regarding unfavorable consumer trends that it was required to make under Items 303 and 105 (formerly 503) of SEC Regulation S-K, 17 C.F.R. §§ 229.303, 229.105. We address each claim in turn.

First, the Investors assert that "[o]n February 8, 2018, Calantzopoulos informed investors 'there's nothing in the horizon that would . . . cause any change in what happened in the previous years' with regard to HeatStick [sales] volume in Japan," during which time PMI "had enjoyed a huge surge in HeatStick-related growth in Japan." Investors Br. at 29 (quoting J. App'x at 2018–19 ¶ 379). That statement, the Investors contend, was revealed "a mere ten weeks" later to have been materially false when made. *Id.* at 30. In particular, they point to an April 2018 earnings call in which then-CFO Martin King, fielding investors' questions about lower-than-expected HeatStick shipments to Japan in 1Q18, acknowledged "anticipating that we would reach some sort of a plateau later in the year, given that we knew the consumer dynamics that we had – close to saturating the early adopters and innovators" – and explained that "[i]t's just coming a bit earlier in the year than what we had foreseen." J. App'x at 1176.

In its decision dismissing the Investors' first amended complaint, the district court found that Calantzopoulos's February 2018 statement "fall[s] under the PSLRA's safe harbor for 'forward[-]looking statements.'" Sp. App'x at 30 (citing 15 U.S.C. § 78u-5). On appeal, the parties vigorously debate the correctness of that legal conclusion. The Investors argue that "Calantzopoulos'[s] *present-tense* statement – 'there is nothing in the horizon' – is . . . not forward[-]looking, as it expressed his *current* understanding that there was nothing 'in the horizon' *at that moment* that would negatively affect HeatStick volumes in Japan." Investors Br. at 29, 31 (quoting J. App'x at 2018–19 ¶ 379) (emphasis added; alteration omitted); *see also id.* at 25 ("[The Investors] do not allege that [D]efendants should have anticipated future events and made certain disclosures earlier, but rather that [D]efendants had *already anticipated* future events and failed to disclose their *then-present awareness*." (emphasis added)). Defendants criticize that "grammatical parsing of Calantzopoulos's statement" as "tortured," and maintain that "[w]hen viewed in context, Calantzopoulos plainly was providing his outlook on the *future* of the . . . Japan[ese] market." Defendants Br. at 41 (emphasis added).

We need not reach the parties' heady debate over the philosophy of language and time, however, as we find that Calantzopoulos's challenged statement was not false *at all* – thus mooting the question of whether it qualifies as a forward-looking statement for purposes of the PSLRA's statutory safe harbor. While the Investors now characterize Calantzopoulos as stating that "'there's nothing in the horizon that would . . . cause any change in what happened in the previous years' *with regard to HeatStick [sales] volume* in Japan," Investors Br. at 29 (quoting J. App'x at 2019 ¶ 379) (emphasis added), that characterization is belied by the record. The transcript of the February 2018 earnings call – as reproduced in the Investors' own complaint – reflects that Calantzopoulos made the challenged statement in direct response to an investor who had asked, "what [are you] thinking in terms of the combustible [cigarette] *plus* the HeatStick volume outlook for Japan?" J. App'x at 2018–19 ¶ 379 (emphasis added). Calantzopoulos answered that "our . . . projection for [the] *total [tobacco] market* in Japan, *including* obviously HeatSticks," is that "there's nothing in the horizon . . . that would cause any change in what happened in the previous years." *Id.* at 2019 ¶ 379 (other emphasis omitted). Indeed, at the beginning of the earnings call, PMI's Vice President of Investor Relations had emphasized that any subsequent

"references to total industry[,] *total market*, PMI volume[,] and PMI market[-]share performance [would] reflect cigarettes *and* heated tobacco units." *Id.* at 1087 (emphasis added).

Considered in that fuller context, the effect of Calantzopoulos's challenged statement is unambiguous. He merely represented that he saw "nothing in the horizon that would . . . cause any change in what happened in the previous years," *id.* at 2019 ¶ 379 (emphasis omitted), with regard to PMI's projected sales volume in the *total* Japanese market for "cigarettes *and* heated tobacco units," *id.* at 1087 (emphasis added) – not "with regard to HeatStick volume in Japan" *alone*, Investors Br. at 29. That representation is fully consistent with King's later statement about "anticipating that [IQOS demand] would reach some sort of a plateau" upon PMI's "saturating the early adopters" and "reaching . . . more conservative . . . *smoker[s]*" who would be "likely to display . . . a slower pace" in transitioning to "the [*smoke-free*-tobacco] category." J. App'x at 1173, 1176 (emphasis added). Meanwhile, the Investors have not alleged that the volume of the *total* Japanese market for combustible *and* heated tobacco products was any smaller in 2018 than it had been in previous years. Nor, for that matter, have they pointed to any statement suggesting that Defendants *anticipated* the total volume

of the Japanese tobacco market to shrink in 2018. As a result, the Investors have failed to plausibly allege any falsity in Calantzopoulos's challenged statement.

Next, the Investors come at King's statement about "anticipating . . . some sort of a plateau [in IQOS demand]," *id.* at 1176, from a slightly different angle. They argue that even if King's admission did not render Calantzopoulos's "nothing-in-the-horizon" statement an actionable falsehood, it would establish that PMI violated its disclosure obligations under Items 303 and 105. More specifically, the Investors contend that under those Items, PMI had a duty "to disclose [in its SEC Forms 10-K and 10-Q] the known uncertainty about 'the level of saturation among the early adopters and innovators in Japan and how that would impact IQOS and HeatStick sales in 2018.'" Investors Br. at 36 (quoting J. App'x at 2030 ¶ 402) (capitalization standardized); *see* 17 C.F.R. § 229.303(b)(2)(ii) (imposing obligation to "[d]escribe any known trends or uncertainties that . . . are reasonably likely to have a material . . . unfavorable impact on net sales or revenues . . . from continuing operations"); *id.* § 229.105(a) (imposing obligation, "where appropriate," to "provide . . . a discussion of the material factors that make an investment in the [company] speculative or risky").

But the Investors overlook the fact that PMI's 10-K and 10-Q Forms throughout the Class Period *did* disclose the very trend that King alluded to "anticipating" – namely, that "more conservative consumers" in "the age[-fifty]-plus smoker segment" would "likely . . . display . . . a slower pace in entering the [smoke-free-tobacco] category" than the relatively younger consumers "in the innovators and early adopters groups." J. App'x at 1173, 1176. For example, in the "Risk Factors" section of its Form 10-K filed January 31, 2018, PMI explained: "[w]e face intense competition, and our failure to compete effectively could have a material adverse effect on our profitability and results of operations. We compete primarily on the basis of . . . , *increasingly, adult[-]smoker willingness to convert to our [smoke-free tobacco products]*." *Id.* at 172 (emphasis added). Similarly, PMI explained that "[t]o be successful, we must . . . *convince adult smokers to convert to our [smoke-free tobacco products]*." *Id.* at 173 (emphasis added).

The Investors argue that these disclosures amounted to "boilerplate," and that Defendants should have more specifically and affirmatively stated that they "knew they were close to reaching" a "plateau in IQOS demand . . . in Japan . . . as a result of the saturation of the younger IQOS user base." Investors Br. at 26

(internal quotation marks omitted; capitalization standardized). But we agree with the district court that any distinction between the disclosures PMI actually made and the disclosures the Investors insist PMI *should have* made is a distinction without a difference: "[a]lthough Defendants did not explicitly frame their disclosure in terms of the risk of saturating the market of early adopters and innovators, their disclosure that they 'increasingly' compete on the basis of 'adult[-]smoker willingness to convert to their [smoke-free products]' describes the flipside of the very same coin." Sp. App'x at 53 (quoting J. App'x at 172) (alteration omitted). As a result, we also agree with the district court's conclusion that the Investors failed to plead any violation of Items 303 or 105 – let alone one that would be actionable under section 10(b) or Rule 10b-5. *See Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 102 (2d Cir. 2015) ("The failure to make a required disclosure under Item 303 . . . is not by itself sufficient to state a claim for securities fraud under [s]ection 10(b)" or "Rule 10b-5," which "make[] only 'material' omissions actionable." (quoting 17 C.F.R. § 240.10b-5(b))).

In an apparent afterthought, the Investors also assert that (1) "Defendants' other statements about growth in Japan were similarly false and misleading . . . . by virtue of [D]efendants' failure to disclose the known slowdown in HeatStick

shipments to Japan by approximately seven billion units in 1Q18," and (2) "[e]ven assuming that any of these statements contain forward-looking aspects, [D]efendants' knowledge of falsity renders them actionable." Investors Br. at 35 (citing J. App'x at 2015–27 ¶¶ 372, 376, 381, 385, 391–93). By "[m]erely mentioning" Defendants' other statements about growth in Japan "in [such] a perfunctory manner, unaccompanied by some effort at developed argumentation," the Investors have abandoned their argument that such statements were actionable. *Niagara Mohawk Power Corp. v. Hudson River-Black River Regul. Dist.*, 673 F.3d 84, 107 (2d Cir. 2012) (citations omitted); *see also Gross v. Rell*, 585 F.3d 72, 95 (2d Cir. 2009); *Tolbert v. Queens Coll.* 242 F.3d 58, 75 (2d Cir. 2001).

To be clear, we do not invoke abandonment as a technicality to justify sidestepping otherwise-meritorious arguments regarding Defendants' other statements about projected growth in Japanese markets. On the contrary, we deem that issue to be abandoned *precisely because* the Investors have failed to make any meaningful – let alone meritorious – argument as to how the district court erred in analyzing it. When Defendants argued that the issue should be "treated

by this Court as waived," Defendants Br. at 44 – or, more precisely, *abandoned*[3] – the Investors responded that the "other statements made by [D]efendants about Japan" were actionable "*for the same [putative] reasons* as the in-the-horizon statement," and that accordingly, they had "no reason to repeat the earlier-made arguments applicable to [such] statements," Reply Br. at 16 (emphasis added). We disagree.

In its February 2020 opinion dismissing the Investors' first amended complaint, the district court found *all* of Defendants' challenged Japan-related statements to be inactionable based on either (1) the PSLRA's statutory safe harbor for forward-looking statements or (2) our closely related doctrine "refus[ing] to allow plaintiffs to proceed with allegations of fraud by hindsight." *Bayerische Landesbank, N.Y. Branch v. Aladdin Cap. Mgmt. LLC*, 692 F.3d 42, 62 (2d Cir. 2012) (internal quotation marks omitted). And indeed, many such statements were worded with *quintessentially* forward-looking language. *Compare, e.g.*, J. App'x at 2015 ¶ 372 ("Continued investment behind IQOS in 2018 is *expected* to further drive

[3] *See United States v. Graham*, 51 F.4th 67, 79–80 (2d Cir. 2022) (discussing distinction between waiver, forfeiture, and abandonment); *see also United States v. Campbell*, 26 F.4th 860, 871–75 (11th Cir. 2022) (en banc) (discussing same, in greater detail).

its positive momentum [in Japan]." (other emphasis omitted)), *and id.* at 2020 ¶ 381 ("[T]he increasing demand for HeatSticks [in Japan is] *anticipated* to further increase in the first quarter of 2018." (other emphasis omitted)), *with* 15 U.S.C. § 78u-5(i)(l)(A)–(C) (PSLRA defining "forward-looking statement[s]" as those regarding "projection[s] of revenues, income . . . , [or] earnings"; "future economic performance"; or "the plans and objectives of management for future operations"), *and In re Bear Stearns Cos. Sec., Derivative, & ERISA Litig.*, 763 F. Supp. 2d 423, 493 (S.D.N.Y. 2011) ("As a general rule, statements whose truth cannot be ascertained until some time after the time they are made are 'forward-looking statements.'" (internal quotation marks omitted)).

Having assessed Calantzopoulos's "nothing-in-the-horizon" statement as presenting the closest call, the Investors made the strategic decision (both in their district-court motion for reconsideration, *see* Dist. Ct. Doc. No. 126 at 9–11, and now in their appellate briefs) to focus on that statement to the exclusion of Defendants' other Japan-related statements. Thus, in challenging the district court's analysis of the PSLRA safe harbor and fraud-by-hindsight doctrine, the Investors have *specifically* relied on the *particular* language of the "nothing-in-the-horizon" statement – arguing that it "recalls precisely 'the Grand-Canyon

scenario[] where a defendant sees disaster looming *on the horizon* but opts to whitewash reality,'" and that it actionably "implie[d] that no . . . problems were *on the horizon* even [though] a precipice was in sight." Investors Br. at 34 (first quoting *Tutor Perini Corp. v. Banc of Am. Sec. LLC*, 842 F.3d 71, 91 (1st Cir. 2016); then quoting *In re Harman Int'l Indus., Inc. Sec. Litig.*, 791 F.3d 90, 102–03 (D.C. Cir. 2015)) (first emphasis added; other internal quotation marks omitted); *see also id.* at 25 (arguing same). These arguments are not "applicable" to the "other statements made by [D]efendants about Japan." Reply Br. at 16.

In sum and substance, then, the Investors have failed to present us with any reason to doubt the correctness of district court's analysis of those statements. It is not for us to play the "initiating role" of conjuring up such reasons on their behalf. *United States v. Sineneng-Smith*, 140 S. Ct. 1575, 1579 (2020); *see also id.* ("[O]n appeal, we rely on the parties to frame the issues for decision and assign to courts the role of neutral arbiter of matters the parties present." (internal quotation marks and alteration omitted)). Accordingly, we will not disturb the district court's well-reasoned conclusion that the balance of "Defendants' positive projections about growth in Japan" either "fall within . . . the [PSLRA] safe harbor for forward-looking statements" or cannot be challenged but by the

"fraud[-]by[-]hindsight approach" that we have "firmly rejected." Sp. App'x at 11, 32, 36 (quoting *Lopez v. CTPartners Exec. Search Inc.*, 173 F. Supp. 3d 12, 24 (S.D.N.Y. 2016) (citing *Stevelman v. Alias Rsch. Inc.*, 174 F.3d 79, 85 (2d Cir. 1999))) (capitalization standardized; other internal quotation marks omitted).

C. Control-Person Liability

Finally, we address the Investors' claim under section 20(a) of the Exchange Act, which imposes joint and several liability on "[e]very person who, directly or indirectly, controls any person liable under any provision of [the Exchange Act] or of any rule or regulation [promulgated] thereunder." 15 U.S.C. § 78t(a). In their operative complaint, the Investors claimed that the Individual Defendants are liable under section 20(a) because they controlled the alleged section 10(b) violators. Because we affirm the district court's dismissal of the Investors' claims under section 10(b) and Rule 10b-5, we must also affirm the dismissal of their claim under section 20(a). *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 108 (2d Cir. 2007) (holding that because "a plaintiff must show . . . a primary violation by the controlled person" in order to "establish a prima facie case of control[-]person liability," a plaintiff who "fails to allege any primary violation . . . cannot establish control[-]person liability").

IV. CONCLUSION

As far as Defendants' challenged statements about the IQOS studies are concerned, the Investors' argument boils down to a charge that PMI engaged in bad science: that the IQOS studies' results were not compelling enough, or their methodology not sound enough, to demonstrate that IQOS is fit to be sold in the United States as a healthier alternative to cigarettes. Certainly, there are scientists – including some of those who *conducted* the IQOS studies – who share the Investors' view. But the FDA scientists who granted PMI's application for a marketing order, granted PMI's application for a reduced-exposure order, and found that PMI was "reasonably likely" to demonstrate eligibility for a reduced-risk order "in subsequent studies," J. App'x at 2975; *see id.* at 3008, are not among them. In a consumer-protection case, a mass tort case, or an administrative-law challenge to the FDA's orders, the views of those FDA scientists might be open to challenge. But in this securities-fraud case, they are conclusive.

All along, the Investors' theory of materiality has been that PMI's "future depended on" securing "FDA[] approval not only to sell IQOS, but also to market it as . . . a product significantly safer than conventional cigarettes," and that the

material effect of Defendants' challenged statements was thus "to assure . . . wary investors . . . . that PMI's clinical trials" could persuade the FDA to grant such approval. Investors Br. at 2, 6 (internal quotation marks omitted; capitalization standardized). To the extent that Defendants' challenged statements were material, the FDA's ultimate rulings proved them to be true. To the extent that Defendants' statements were *otherwise* false, they were immaterial. That is fatal to the Investors' securities-fraud claim: it is axiomatic that "[n]either immaterial false statements nor material true statements are actionable." *In re Lululemon*, 14 F. Supp. 3d at 571 (citing *Basic*, 485 U.S. at 238), *aff'd*, 604 F. App'x 62.

As to Defendants' statements about their projections for IQOS's performance in Japanese markets, the Investors' argument reduces to a charge that Defendants should have "take[n] a [more] gloomy, fearful[,] or defeatist view of the future" and expressed less "confiden[ce] about their stewardship and the prospects of the business that they manage." *Rombach*, 355 F.3d at 174 (internal quotation marks omitted). We have repeatedly rejected the notion that the securities laws require the "[p]eople in charge of an enterprise" to adopt such a view, and we reject it again here. *Id.* (internal quotation marks omitted)

For the foregoing reasons, we **AFFIRM** the judgment of the district court.