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MATRIXX INITIATIVES, INC., ET AL. *v.* SIRACUSANO ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

No. 09–1156. Argued January 10, 2011—Decided March 22, 2011

[redacted]

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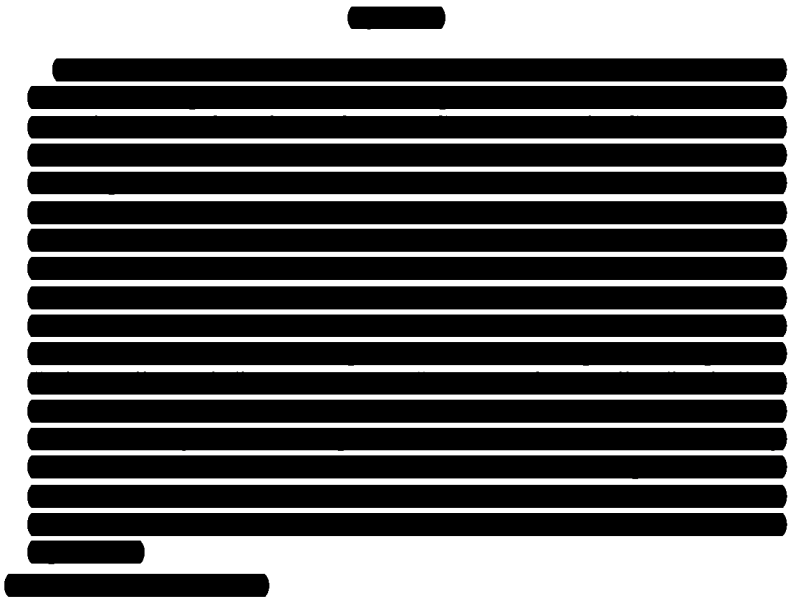

SOTOMAYOR, J., delivered the opinion for a unanimous Court.

Jonathan D. Hacker argued the cause for petitioners. With him on the briefs were *Matthew Shors*, *Irving L. Gornstein*, *Michael G. Yoder*, and *Amy J. Longo*.

David C. Frederick argued the cause for respondents. With him on the brief were *Scott H. Angstreich*, *Gregory G. Rapawy*, *Eric Alan Isaacson*, and *Joseph D. Daley*.

Pratik A. Shah argued the cause for the United States as *Amicus Curiae* in support of respondents. With him on the brief were *Acting Solicitor General Katyal*, *Deputy Solicitor General Stewart*, *David M. Becker*, *Mark D. Cahn*, *Jacob H. Stillman*, *Michael A. Conley*, *Luis de la Torre*, *Jeffrey A. Berger*, and *Ralph S. Tyler*.*

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*Briefs of *amici curiae* urging reversal were filed for the Advanced Medical Technology Association by *Steven G. Bradbury*, *Steven A. Engel*, *James M. Beck*, and *David A. Kotler*; for BayBio by *Deanne E. Maynard*, *Brian R. Matsui*, and *Marc A. Hearron*; for the Consumer Healthcare Products Association et al. by *Robert A. Long, Jr.*, and *Richard F. Kingham*; for DRI—The Voice of the Defense Bar by *James C. Martin* and

JUSTICE SOTOMAYOR delivered the opinion of the Court.

This case presents the question whether a plaintiff can state a claim for securities fraud under § 10(b) of the Securities Exchange Act of 1934, 48 Stat. 891, as amended, 15 U. S. C. § 78j(b), and Securities and Exchange Commission (SEC) Rule 10b–5, 17 CFR § 240.10b–5 (2010), based on a pharmaceutical company's failure to disclose reports of adverse events associated with a product if the reports do not disclose a statistically significant number of adverse events. Respondents, plaintiffs in a securities fraud class action, allege that petitioners, Matrixx Initiatives, Inc., and three of its executives (collectively Matrixx), failed to disclose reports of a possible link between Matrixx's leading product, a cold remedy, and loss of smell, rendering statements made by Matrixx misleading. Matrixx contends that respondents' complaint does not adequately allege that Matrixx made a material representation or omission or that it acted with scienter because the complaint does not allege that Matrixx knew of a statistically significant number of adverse events requiring disclosure. We conclude that the materiality of adverse event reports cannot be reduced to a bright-line rule. Although in many cases reasonable investors would not con-

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Colin E. Wrabley; for the Natural Products Association by *Scott Bass* and *Jonathan F. Cohn;* for the Pharmaceutical Research and Manufacturers of America et al. by *David W. Ogden* and *Mark C. Fleming;* for the Product Liability Advisory Council, Inc., by *Anne E. Cohen;* for the Securities Industry and Financial Markets Association et al. by *Lyle Roberts*, *Jonathan E. Richman*, *Kevin M. Carroll*, *Robin S. Conrad*, and *Amar D. Sarwal;* and for the Washington Legal Foundation by *Daniel J. Popeo* and *Richard A. Samp.*

Briefs of *amici curiae* urging affirmance were filed for AARP et al. by *Jay E. Sushelsky* and *Michael R. Schuster;* for Robert E. Litan et al. by *Merrill G. Davidoff* and *Lawrence J. Lederer;* for Tonia M. Young-Fadok et al. by *Jonathan S. Massey*, *Jay W. Eisenhofer*, *Geoffrey C. Jarvis*, *David Kessler*, *Darren J. Check*, and *Benjamin J. Sweet;* for Professors at Law and Business Schools by *J. Robert Brown, Jr.*, *Lisa L. Casey*, and *Robert O. Bentley;* and for Statistics Experts by *Edward Labaton.*

sider reports of adverse events to be material information, respondents have alleged facts plausibly suggesting that reasonable investors would have viewed these particular reports as material. Respondents have also alleged facts "giving rise to a strong inference" that Matrixx "acted with the required state of mind." 15 U. S. C. § 78u–4(b)(2)(A) (2006 ed., Supp. IV). We therefore hold, in agreement with the Court of Appeals for the Ninth Circuit, that respondents have stated a claim under § 10(b) and Rule 10b–5.

I

A

Through a wholly owned subsidiary, Matrixx develops, manufactures, and markets over-the-counter pharmaceutical products. Its core brand of products is called Zicam. All of the products sold under the name Zicam are used to treat the common cold and associated symptoms. At the time of the events in question, one of Matrixx's products was Zicam Cold Remedy, which came in several forms including nasal spray and gel. The active ingredient in Zicam Cold Remedy was zinc gluconate. Respondents allege that Zicam Cold Remedy accounted for approximately 70 percent of Matrixx's sales.

Respondents initiated this securities fraud class action against Matrixx on behalf of individuals who purchased Matrixx securities between October 22, 2003, and February 6, 2004.[1] The action principally arises out of statements that Matrixx made during the class period relating to revenues and product safety. Respondents claim that Matrixx's statements were misleading in light of reports that Matrixx had received, but did not disclose, about consumers who had lost their sense of smell (a condition called anosmia) after using Zicam Cold Remedy. Respondents' consolidated amended

[1] According to the complaint, Matrixx securities were traded on the NASDAQ National Market. App. 99a.

complaint alleges the following facts, which the courts below properly assumed to be true. See *Ashcroft* v. *Iqbal*, 556 U. S. 662, 678 (2009).

In 1999, Dr. Alan Hirsch, neurological director of the Smell & Taste Treatment and Research Foundation, Ltd., called Matrixx's customer service line after discovering a possible link between Zicam nasal gel and a loss of smell "in a cluster of his patients." App. 67a–68a. Dr. Hirsch told a Matrixx employee that "previous studies had demonstrated that intranasal application of zinc could be problematic." *Id.*, at 68a. He also told the employee about at least one of his patients who did not have a cold and who developed anosmia after using Zicam.

In September 2002, Timothy Clarot, Matrixx's vice president for research and development, called Miriam Linschoten, Ph.D., at the University of Colorado Health Sciences Center after receiving a complaint from a person Linschoten was treating who had lost her sense of smell after using Zicam. Clarot informed Linschoten that Matrixx had received similar complaints from other customers. Linschoten drew Clarot's attention to "previous studies linking zinc sulfate to loss of smell." *Ibid.* Clarot gave her the impression that he had not heard of the studies. She asked Clarot whether Matrixx had done any studies of its own; he responded that it had not but that it had hired a consultant to review the product. Soon thereafter, Linschoten sent Clarot abstracts of the studies she had mentioned. Research from the 1930's and 1980's had confirmed "[z]inc's toxicity." *Id.*, at 69a. Clarot called Linschoten to ask whether she would be willing to participate in animal studies that Matrixx was planning, but she declined because her focus was human research.

By September 2003, one of Linschoten's colleagues at the University of Colorado, Dr. Bruce Jafek, had observed 10 patients suffering from anosmia after Zicam use. Linschoten and Jafek planned to present their findings at a meeting

of the American Rhinologic Society in a poster presentation entitled "Zicam® Induced Anosmia." *Ibid.* (internal quotation marks omitted). The American Rhinologic Society posted their abstract in advance of the meeting. The presentation described in detail a 55-year-old man with previously normal taste and smell who experienced severe burning in his nose, followed immediately by a loss of smell, after using Zicam. It also reported 10 other Zicam users with similar symptoms.

Matrixx learned of the doctors' planned presentation. Clarot sent a letter to Dr. Jafek warning him that he did not have permission to use Matrixx's name or the names of its products. Dr. Jafek deleted the references to Zicam in the poster before presenting it to the American Rhinologic Society.

The following month, two plaintiffs commenced a product liability lawsuit against Matrixx alleging that Zicam had damaged their sense of smell. By the end of the class period on February 6, 2004, nine plaintiffs had filed four lawsuits.

Respondents allege that Matrixx made a series of public statements that were misleading in light of the foregoing information. In October 2003, after it had learned of Dr. Jafek's study and after Dr. Jafek had presented his findings to the American Rhinologic Society, Matrixx stated that Zicam was "'poised for growth in the upcoming cough and cold season'" and that the company had "'very strong momentum.'"[2] *Id.*, at 72a–74a. Matrixx further expressed its expectation that revenues would "'be up in excess of 50% and that earnings, per share for the full year [would] be in the 25 to 30 cent range.'" *Id.*, at 74a. In January 2004, Matrixx raised

[2] At oral argument, counsel for the United States, which submitted an *amicus curiae* brief in support of respondents, suggested that some of these statements might qualify as nonactionable "puffery." Tr. of Oral Arg. 51–52. This question is not before us, as Matrixx has not advanced such an argument.

its revenue guidance, predicting an increase in revenues of 80 percent and earnings per share in the 33- to 38-cent range.

In its Form 10–Q filed with the SEC in November 2003, Zicam warned of the potential "'material adverse effect'" that could result from product liability claims, "'whether or not proven to be valid.'" *Id.*, at 75a–76a. It stated that product liability actions could materially affect Matrixx's "'product branding and goodwill,'" leading to reduced customer acceptance.[3] *Id.*, at 76a. It did not disclose, however, that two plaintiffs had already sued Matrixx for allegedly causing them to lose their sense of smell.

On January 30, 2004, Dow Jones Newswires reported that the Food and Drug Administration (FDA) was "'looking into complaints that an over-the-counter common-cold medicine manufactured by a unit of Matrixx Initiatives, Inc. (MTXX) may be causing some users to lose their sense of smell'" in light of at least three product liability lawsuits. *Id.*, at 79a–80a. Matrixx's stock fell from $13.55 to $11.97 per share after the report. In response, on February 2, Matrixx issued a press release that stated:

> "All Zicam products are manufactured and marketed according to FDA guidelines for homeopathic medicine. Our primary concern is the health and safety of our customers and the distribution of factual information about our products. Matrixx believes statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading.
>
> "In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell). Rather, the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well

[3] Respondents also allege that Matrixx falsely reported its financial results in the Form 10–Q by failing to reserve for or disclose potential liability, in violation of generally accepted accounting principles. The Court of Appeals did not rely on these allegations.

established in two double-blind, placebo-controlled, randomized clinical trials. In fact, in neither study were there any reports of anosmia related to the use of this compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.

"A multitude of environmental and biologic influences are known to affect the sense of smell. Chief among them is the common cold. As a result, the population most likely to use cold remedy products is already at increased risk of developing anosmia. Other common causes of olfactory dysfunction include age, nasal and sinus infections, head trauma, anatomical obstructions, and environmental irritants." *Id.*, at 77a–78a (internal quotation marks omitted).

The day after Matrixx issued this press release, its stock price bounced back to $13.40 per share.

On February 6, 2004, the end of the class period, Good Morning America, a nationally broadcast morning news program, highlighted Dr. Jafek's findings. (The complaint does not allege that Matrixx learned of the news story before its broadcast.) The program reported that Dr. Jafek had discovered more than a dozen patients suffering from anosmia after using Zicam. It also noted that four lawsuits had been filed against Matrixx. The price of Matrixx stock plummeted to $9.94 per share that same day. Zicam again issued a press release largely repeating its February 2 statement.

On February 19, 2004, Matrixx filed a Form 8–K with the SEC stating that it had "'convened a two-day meeting of physicians and scientists to review current information on smell disorders'" in response to Dr. Jafek's presentation. *Id.*, at 82a. According to the Form 8–K: "'In the opinion of the panel, there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell.'" *Ibid.* A few weeks

later, a reporter quoted Matrixx as stating that it would begin conducting "'animal and human studies to further characterize these post-marketing complaints.'" *Id.*, at 84a.

On the basis of these allegations, respondents claimed that Matrixx violated § 10(b) of the Securities Exchange Act and SEC Rule 10b–5 by making untrue statements of fact and failing to disclose material facts necessary to make the statements not misleading in an effort to maintain artificially high prices for Matrixx securities.

B

Matrixx moved to dismiss respondents' complaint, arguing that they had failed to plead the elements of a material misstatement or omission and scienter. The District Court granted the motion to dismiss. Relying on *In re Carter-Wallace, Inc. Securities Litigation*, 220 F. 3d 36 (CA2 2000), it held that respondents had not alleged a "statistically significant correlation between the use of Zicam and anosmia so as to make failure to public[ly] disclose complaints and the University of Colorado study a material omission." App. to Pet. for Cert. 50a. The District Court similarly agreed that respondents had not stated with particularity facts giving rise to a strong inference of scienter. See 15 U. S. C. § 78u–4(b)(2)(A). It noted that the complaint failed to allege that Matrixx disbelieved its statements about Zicam's safety or that any of the defendants profited or attempted to profit from Matrixx's public statements. App. to Pet. for Cert. 52a.

The Court of Appeals reversed. 585 F. 3d 1167 (CA9 2009). Noting that "'[t]he determination [of materiality] requires delicate assessments of the inferences a "reasonable shareholder" would draw from a given set of facts and the significance of those inferences to him,'" *id.*, at 1178 (quoting *Basic Inc.* v. *Levinson*, 485 U. S. 224, 236 (1988); some internal quotation marks omitted; alterations in original), the Court of Appeals held that the District Court had erred in

requiring an allegation of statistical significance to establish materiality. It concluded, to the contrary, that the complaint adequately alleged "information regarding the possible link between Zicam and anosmia" that would have been significant to a reasonable investor. 585 F. 3d, at 1179, 1180. Turning to scienter, the Court of Appeals concluded that "[w]ithholding reports of adverse effects of and lawsuits concerning the product responsible for the company's remarkable sales increase is 'an extreme departure from the standards of ordinary care,' " giving rise to a strong inference of scienter. *Id.*, at 1183.

We granted certiorari, 560 U. S. 964 (2010), and we now affirm.

II

Section 10(b) of the Securities Exchange Act makes it unlawful for any person to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U. S. C. § 78j(b). SEC Rule 10b–5 implements this provision by making it unlawful to, among other things, "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 CFR § 240.10b–5(b). We have implied a private cause of action from the text and purpose of § 10(b). See *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U. S. 308, 318 (2007).

To prevail on their claim that Matrixx made material misrepresentations or omissions in violation of § 10(b) and Rule 10b–5, respondents must prove "(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 Investment Partners, LLC* v. *Scientific-Atlanta, Inc.*, 552 U. S. 148, 157 (2008). Matrixx contends that respondents have failed to plead both the element of a material misrepresentation or omission and the element of scienter because they have not alleged that the reports received by Matrixx reflected statistically significant evidence that Zicam caused anosmia. We disagree.

A

We first consider Matrixx's argument that "adverse event reports that do not reveal a statistically significant increased risk of adverse events from product use are not material information." Brief for Petitioners 17 (capitalization omitted).

1

To prevail on a § 10(b) claim, a plaintiff must show that the defendant made a statement that was "*misleading* as to a *material* fact."[4] *Basic*, 485 U. S., at 238. In *Basic*, we held that this materiality requirement is satisfied when there is "'a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.'" *Id.*, at 231–232 (quoting *TSC Industries, Inc.* v. *Northway, Inc.*, 426 U. S. 438, 449 (1976)). We were "careful not to set too low a standard of materiality," for fear that management would "'bury the shareholders in an avalanche of trivial information.'" 485 U. S., at 231 (quoting *TSC Industries*, 426 U. S., at 448–449).

Basic involved a claim that the defendant had made misleading statements denying that it was engaged in merger negotiations when it was, in fact, conducting preliminary ne-

[4] Under the Private Securities Litigation Reform Act of 1995 (PSLRA), when a plaintiff's claim is based on alleged misrepresentations or omissions of a material fact, "the complaint shall specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U. S. C. § 78u–4(b)(1).

gotiations. See 485 U. S., at 227–229. The defendant urged a bright-line rule that preliminary merger negotiations are material only once the parties to the negotiations reach an agreement in principle. *Id.*, at 232–233. We observed that "[a]ny approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be overinclusive or underinclusive." *Id.*, at 236. We thus rejected the defendant's proposed rule, explaining that it would "artificially exclud[e] from the definition of materiality information concerning merger discussions, which would otherwise be considered significant to the trading decision of a reasonable investor." *Ibid.*

Like the defendant in *Basic*, Matrixx urges us to adopt a bright-line rule that reports of adverse events[5] associated with a pharmaceutical company's products cannot be material absent a sufficient number of such reports to establish a statistically significant risk that the product is in fact causing the events.[6] Absent statistical significance, Matrixx argues,

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[5] The FDA defines an "[a]dverse drug experience" as "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related." 21 CFR § 314.80(a) (2010). Federal law imposes certain obligations on pharmaceutical manufacturers to report adverse events to the FDA. During the class period, manufacturers of over-the-counter drugs such as Zicam Cold Remedy had no obligation to report adverse events to the FDA. In 2006, Congress enacted legislation to require manufacturers of over-the-counter drugs to report any "serious adverse event" to the FDA within 15 business days. See 21 U. S. C. §§ 379aa(b), (c).

[6] "A study that is statistically significant has results that are unlikely to be the result of random error . . . ." Federal Judicial Center, Reference Manual on Scientific Evidence 354 (2d ed. 2000). To test for significance, a researcher develops a "null hypothesis"—*e. g.*, the assertion that there is no relationship between Zicam use and anosmia. See *id.*, at 122. The researcher then calculates the probability of obtaining the observed data (or more extreme data) if the null hypothesis is true (called the *p*-value). *Ibid.* Small *p*-values are evidence that the null hypothesis is incorrect. See *ibid.* Finally, the researcher compares the *p*-value to a preselected

adverse event reports provide only "anecdotal" evidence that "the user of a drug experienced an adverse event at some point during or following the use of that drug." Brief for Petitioners 17. Accordingly, it contends, reasonable investors would not consider such reports relevant unless they are statistically significant because only then do they "reflect a scientifically reliable basis for inferring a potential causal link between product use and the adverse event." *Id.*, at 32.

As in *Basic*, Matrixx's categorical rule would "artificially exclud[e]" information that "would otherwise be considered significant to the trading decision of a reasonable investor." 485 U. S., at 236. Matrixx's argument rests on the premise that statistical significance is the only reliable indication of causation. This premise is flawed: As the SEC points out, "medical researchers . . . consider multiple factors in assessing causation." Brief for United States as *Amicus Curiae* 12. Statistically significant data are not always available. For example, when an adverse event is subtle or rare, "an inability to obtain a data set of appropriate quality or quantity may preclude a finding of statistical significance." *Id.*, at 15; see also Brief for Medical Researchers as *Amici Curiae* 11. Moreover, ethical considerations may prohibit researchers from conducting randomized clinical trials to confirm a suspected causal link for the purpose of obtaining statistically significant data. See *id.*, at 10–11.

A lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events. As Matrixx itself concedes, medical experts rely on other evidence to establish an inference of causation. See Brief for Petitioners 44–45, n. 22.[7] We note that courts frequently permit expert testi-

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value called the significance level. *Id.*, at 123. If the *p*-value is below the preselected value, the difference is deemed "significant." *Id.*, at 124.

[7] Matrixx and its *amici* list as relevant factors the strength of the association between the drug and the adverse effects; a temporal relationship between exposure and the adverse event; consistency across studies; bio-

mony on causation based on evidence other than statistical significance. See, *e. g.*, *Best* v. *Lowe's Home Centers, Inc.*, 563 F. 3d 171, 178 (CA6 2009); *Westberry* v. *Gislaved Gummi AB*, 178 F. 3d 257, 263–264 (CA4 1999) (citing cases); *Wells* v. *Ortho Pharmaceutical Corp.*, 788 F. 2d 741, 744–745 (CA11 1986). We need not consider whether the expert testimony was properly admitted in those cases, and we do not attempt to define here what constitutes reliable evidence of causation. It suffices to note that, as these courts have recognized, "medical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence." Brief for Medical Researchers as *Amici Curiae* 31.

The FDA similarly does not limit the evidence it considers for purposes of assessing causation and taking regulatory action to statistically significant data. In assessing the safety risk posed by a product, the FDA considers factors such as "strength of the association," "temporal relationship of product use and the event," "consistency of findings across available data sources," "evidence of a dose-response for the effect," "biologic plausibility," "seriousness of the event relative to the disease being treated," "potential to mitigate the risk in the population," "feasibility of further study using observational or controlled clinical study designs," and "degree of benefit the product provides, including availability of other therapies."[8] FDA, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment 18 (2005) (capitalization omitted), http://

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logical plausibility; consideration of alternative explanations; specificity (*i. e.*, whether the specific chemical is associated with the specific disease); the dose-response relationship; and the clinical and pathological characteristics of the event. Brief for Petitioners 44–45, n. 22; Brief for Consumer Healthcare Products Association et al. as *Amici Curiae* 12–13. These factors are similar to the factors the FDA considers in taking action against pharmaceutical products. See *infra* this page.

[8] See also n. 7, *supra.*

www.fda.gov/downloads/RegulatingInformation/Guidances/UCM126834.pdf (all Internet materials as visited Mar. 17, 2011, and available in Clerk of Court's case file); see also Brief for United States as *Amicus Curiae* 19–20 (same); FDA, The Clinical Impact of Adverse Event Reporting 6 (1996) (similar), http://www.fda.gov/downloads/safety/MedWatch/UCM168505.pdf. It "does not apply any single metric for determining when additional inquiry or action is necessary, and it certainly does not insist upon 'statistical significance.'" Brief for United States as *Amicus Curiae* 19.

Not only does the FDA rely on a wide range of evidence of causation, it sometimes acts on the basis of evidence that suggests, but does not prove, causation. For example, the FDA requires manufacturers of over-the-counter drugs to revise their labeling "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." 21 CFR §201.80(e). More generally, the FDA may make regulatory decisions against drugs based on postmarketing evidence that gives rise to only a suspicion of causation. See FDA, The Clinical Impact of Adverse Event Reporting, *supra*, at 7 ("[A]chieving certain proof of causality through postmarketing surveillance is unusual. Attaining a prominent degree of suspicion is much more likely, and may be considered a sufficient basis for regulatory decisions" (footnote omitted)).[9]

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[9] See also GAO, M. Crosse et al., Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process 7 (GAO–06–402, 2006) ("If FDA has information that a drug on the market may pose a significant health risk to consumers, it weighs the effect of the adverse events against the benefit of the drug to determine what actions, if any, are warranted. This decision-making process is complex and encompasses many factors, such as the medical importance and utility of the drug, the drug's extent of usage, the severity of the disease being treated, the drug's efficacy in treating this disease, and the availability of other drugs to treat the same disorder"), http://www.gao.gov/new.items/

This case proves the point. In 2009, the FDA issued a warning letter to Matrixx stating that "[a] significant and growing body of evidence substantiates that the Zicam Cold Remedy intranasal products may pose a serious risk to consumers who use them." App. 270a. The letter cited as evidence 130 reports of anosmia the FDA had received, the fact that the FDA had received few reports of anosmia associated with other intranasal cold remedies, and "evidence in the published scientific literature that various salts of zinc can damage olfactory function in animals and humans." *Ibid.* It did not cite statistically significant data.

Given that medical professionals and regulators act on the basis of evidence of causation that is not statistically significant, it stands to reason that in certain cases reasonable investors would as well. As Matrixx acknowledges, adverse event reports "appear in many forms, including direct complaints by users to manufacturers, reports by doctors about reported or observed patient reactions, more detailed case reports published by doctors in medical journals, or larger scale published clinical studies." Brief for Petitioners 17. As a result, assessing the materiality of adverse event reports is a "fact-specific" inquiry, *Basic*, 485 U. S., at 236, that requires consideration of the source, content, and context of the reports. This is not to say that statistical significance (or the lack thereof) is irrelevant—only that it is not dispositive of every case.

Application of *Basic*'s "total mix" standard does not mean that pharmaceutical manufacturers must disclose all reports of adverse events. Adverse event reports are daily events in the pharmaceutical industry; in 2009, the FDA entered nearly 500,000 such reports into its reporting system, see FDA, Reports Received and Reports Entered in AERS

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d06402.pdf; Federal Judicial Center, *supra* n. 6, at 33 ("[R]isk assessors may pay heed to any evidence that points to a need for caution, rather than assess the likelihood that a causal relationship in a specific case is more likely than not").

by Year (as of Mar. 31, 2010), http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm. The fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event. See FDA, Annual Adverse Drug Experience Report: 1996, p. 2 (1997), http://druganddevicelaw.net/Annual%20Adverse%20Drug%20Experience%20Report%201996.pdf. The question remains whether a *reasonable* investor would have viewed the nondisclosed information "'as having *significantly* altered the "total mix" of information made available.'" *Basic*, 485 U. S., at 232 (quoting *TSC Industries*, 426 U. S., at 449; emphasis added). For the reasons just stated, the mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the adverse events—will not satisfy this standard. Something more is needed, but that something more is not limited to statistical significance and can come from "the source, content, and context of the reports," *supra*, at 43. This contextual inquiry may reveal in some cases that reasonable investors would have viewed reports of adverse events as material even though the reports did not provide statistically significant evidence of a causal link.[10]

Moreover, it bears emphasis that § 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary "to make . . . statements made, in the light of the circumstances under which they were made, not misleading." 17 CFR § 240.10b–5(b); see also

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[10] We note that our conclusion accords with views of the SEC, as expressed in an *amicus curiae* brief filed in this case. See Brief for United States 11–12; see also *TSC Industries, Inc.* v. *Northway, Inc.*, 426 U. S. 438, 449, n. 10 (1976) ("[T]he SEC's view of the proper balance between the need to insure adequate disclosure and the need to avoid the adverse consequences of setting too low a threshold for civil liability is entitled to consideration").

Basic, 485 U. S., at 239, n. 17 ("Silence, absent a duty to disclose, is not misleading under Rule 10b–5"). Even with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these provisions by controlling what they say to the market.

2

Applying *Basic*'s "total mix" standard in this case, we conclude that respondents have adequately pleaded materiality. This is not a case about a handful of anecdotal reports, as Matrixx suggests. Assuming the complaint's allegations to be true, as we must, Matrixx received information that plausibly indicated a reliable causal link between Zicam and anosmia. That information included reports from three medical professionals and researchers about more than 10 patients who had lost their sense of smell after using Zicam. Clarot told Linschoten that Matrixx had received additional reports of anosmia. (In addition, during the class period, nine plaintiffs commenced four product liability lawsuits against Matrixx alleging a causal link between Zicam use and anosmia.)[11] Further, Matrixx knew that Linschoten and Dr. Jafek had presented their findings about a causal link between Zicam and anosmia to a national medical conference devoted to treatment of diseases of the nose.[12] Their presentation described a patient who experienced severe burning

[11] It is unclear whether these plaintiffs were the same individuals whose symptoms were reported by the medical professionals.

[12] Matrixx contends that Dr. Jafek and Linschoten's study was not reliable because they did not sufficiently rule out the common cold as a cause for their patients' anosmia. We note that the complaint alleges that, in one instance, a consumer who did not have a cold lost his sense of smell after using Zicam. More importantly, to survive a motion to dismiss, respondents need only allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp.* v. *Twombly*, 550 U. S. 544, 570 (2007). For all the reasons we state in the opinion, respondents' allegations plausibly suggest that Dr. Jafek and Linschoten's conclusions were based on reliable evidence of a causal link between Zicam and anosmia.

in his nose, followed immediately by a loss of smell, after using Zicam—suggesting a temporal relationship between Zicam use and anosmia.

Critically, both Dr. Hirsch and Linschoten had also drawn Matrixx's attention to previous studies that had demonstrated a biological causal link between intranasal application of zinc and anosmia.[13] Before his conversation with Linschoten, Clarot, Matrixx's vice president of research and development, was seemingly unaware of these studies, and the complaint suggests that, as of the class period, Matrixx had not conducted any research of its own relating to anosmia. See, *e. g.*, App. 84a (referencing a press report, issued after the end of the class period, noting that Matrixx said it would begin conducting " 'animal and human studies to further characterize these post-marketing complaints' "). Accordingly, it can reasonably be inferred from the complaint that Matrixx had no basis for rejecting Dr. Jafek's findings out of hand.

We believe that these allegations suffice to "raise a reasonable expectation that discovery will reveal evidence" satisfying the materiality requirement, *Bell Atlantic Corp.* v. *Twombly*, 550 U. S. 544, 556 (2007), and to "allo[w] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged," *Iqbal*, 556 U. S., at 678. The information provided to Matrixx by medical experts revealed a plausible causal relationship between Zicam Cold

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[13] Matrixx contends that these studies are not reliable evidence of causation because the studies used zinc sulfate, whereas the active ingredient in Matrixx is zinc gluconate. Respondents' complaint, however, alleges that the studies confirmed the toxicity of "zinc." App. 68a. Matrixx further contends that studies relating to fish cannot reliably prove causation with respect to humans. The complaint references several studies, however, only one of which involved fish. In any event, the existence of the studies suggests a plausible biological link between zinc and anosmia, which, in combination with the other allegations, is sufficient to survive a motion to dismiss.

Remedy and anosmia. Consumers likely would have viewed the risk associated with Zicam (possible loss of smell) as substantially outweighing the benefit of using the product (alleviating cold symptoms), particularly in light of the existence of many alternative products on the market. Importantly, Zicam Cold Remedy allegedly accounted for 70 percent of Matrixx's sales. Viewing the allegations of the complaint as a whole, the complaint alleges facts suggesting a significant risk to the commercial viability of Matrixx's leading product.

It is substantially likely that a reasonable investor would have viewed this information "'as having significantly altered the "total mix" of information made available.'" *Basic*, 485 U. S., at 232 (quoting *TSC Industries*, 426 U. S., at 449). Matrixx told the market that revenues were going to rise 50 and then 80 percent. Assuming the complaint's allegations to be true, however, Matrixx had information indicating a significant risk to its leading revenue-generating product. Matrixx also stated that reports indicating that Zicam caused anosmia were "'completely unfounded and misleading'" and that "'the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established.'" App. 77a–78a. Importantly, however, Matrixx had evidence of a biological link between Zicam's key ingredient and anosmia, and it had not conducted any studies of its own to disprove that link. In fact, as Matrixx later revealed, the scientific evidence at that time was "'insufficient . . . to determine if zinc gluconate, when used as recommended, affects a person's ability to smell.'" *Id.*, at 82a.

Assuming the facts to be true, these were material facts "necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 CFR §240.10b–5(b). We therefore affirm the Court of Appeals' holding that respondents adequately pleaded the element of a material misrepresentation or omission.

B

Matrixx also argues that respondents failed to allege facts plausibly suggesting that it acted with the required level of scienter. "To establish liability under § 10(b) and Rule 10b–5, a private plaintiff must prove that the defendant acted with scienter, 'a mental state embracing intent to deceive, manipulate, or defraud.'" *Tellabs*, 551 U. S., at 319 (quoting *Ernst & Ernst* v. *Hochfelder*, 425 U. S. 185, 193–194, and n. 12 (1976)). We have not decided whether recklessness suffices to fulfill the scienter requirement. See *Tellabs*, 551 U. S., at 319, n. 3. Because Matrixx does not challenge the Court of Appeals' holding that the scienter requirement may be satisfied by a showing of "deliberate recklessness," see 585 F. 3d, at 1180 (internal quotation marks omitted), we assume, without deciding, that the standard applied by the Court of Appeals is sufficient to establish scienter.[14]

Under the PSLRA, a plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U. S. C. § 78u–4(b)(2)(A) (2006 ed., Supp. IV). This standard requires courts to take into account "plausible opposing inferences." *Tellabs*, 551 U. S., at 323. A complaint adequately pleads scienter under the PSLRA "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*, at 324. In making this determination, the court must review "all the allegations holistically." *Id.*, at 326. The absence of a motive allegation, though relevant, is not dispositive. *Id.*, at 325.

Matrixx argues, in summary fashion, that because respondents do not allege that it knew of statistically significant evidence of causation, there is no basis to consider the

[14] Under the PSLRA, if the alleged misstatement or omission is a "forward-looking statement," the required level of scienter is "actual knowledge." 15 U. S. C. § 78u–5(c)(1)(B). Matrixx has not argued that the statements or omissions here are "forward-looking statement[s]."

inference that it acted recklessly or knowingly to be at least as compelling as the alternative inferences. "Rather," it argues, "the most obvious inference is that petitioners did not disclose the [reports] simply because petitioners believed they were far too few . . . to indicate anything meaningful about adverse reactions to use of Zicam." Brief for Petitioners 49. Matrixx's proposed bright-line rule requiring an allegation of statistical significance to establish a strong inference of scienter is just as flawed as its approach to materiality.

The inference that Matrixx acted recklessly (or intentionally, for that matter) is at least as compelling as, if not more compelling than, the inference that it simply thought the reports did not indicate anything meaningful about adverse reactions. According to the complaint, Matrixx was sufficiently concerned about the information it received that it informed Linschoten that it had hired a consultant to review the product, asked Linschoten to participate in animal studies, and convened a panel of physicians and scientists in response to Dr. Jafek's presentation. It successfully prevented Dr. Jafek from using Zicam's name in his presentation on the ground that he needed Matrixx's permission to do so. Most significantly, Matrixx issued a press release that suggested that studies had confirmed that Zicam does not cause anosmia when, in fact, it had not conducted any studies relating to anosmia and the scientific evidence at that time, according to the panel of scientists, was insufficient to determine whether Zicam did or did not cause anosmia.[15]

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[15] One of Matrixx's *amici* argues that "the most cogent inference regarding Matrixx's state of mind is that it delayed releasing information regarding anosmia complaints in order to provide itself an opportunity to carefully review all evidence regarding any link between Zicam and anosmia." Brief for Washington Legal Foundation 26. We do not doubt that this may be the most cogent inference in some cases. Here, however, the misleading nature of Matrixx's press release is sufficient to render the inference of scienter at least as compelling as the inference suggested by *amicus*.

These allegations, "taken collectively," give rise to a "cogent and compelling" inference that Matrixx elected not to disclose the reports of adverse events not because it believed they were meaningless but because it understood their likely effect on the market. *Tellabs*, 551 U. S., at 323, 324. "[A] reasonable person" would deem the inference that Matrixx acted with deliberate recklessness (or even intent) "at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*, at 324. We conclude, in agreement with the Court of Appeals, that respondents have adequately pleaded scienter. Whether respondents can ultimately prove their allegations and establish scienter is an altogether different question.

* * *

For the reasons stated, the judgment of the Court of Appeals for the Ninth Circuit is

Affirmed.