No. 09-1156

In the Supreme Court of the United States

MATRIXX INITIATIVES, INC., ET AL., PETITIONERS

v.

JAMES SIRACUSANO, ET AL.

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS

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QUESTION PRESENTED

Petitioner Matrixx Initiatives Inc. (Matrixx) sold an intranasally applied cold remedy (Zicam) that accounted for 70% of Matrixx's sales. Matrixx shareholders (respondents in this Court) allege that Matrixx violated Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. 78j(b), and Rule 10b-5, 17 C.F.R. 240.10b-5, by touting Zicam's expected success and safety without disclosing, among other pertinent information, reports from physicians and researchers that some users had suffered a loss of their sense of smell (anosmia) after using Zicam. On the day that such reports became public, Matrixx's stock price dropped 23.8%. The question presented is as follows:

Whether, in order to state a Section 10(b) claim based on Matrixx's failure to disclose information regarding the possible association between use of Zicam and anosmia, respondents were required to allege evidence of a "statistically significant" association.

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INTEREST OF THE UNITED STATES

The United States, through the Department of Justice and the Securities and Exchange Commission (SEC), administers and enforces the federal securities laws, including the laws at issue in this case, Section 10(b) of the Securities Exchange Act of 1934 (Exchange Act), 15 U.S.C. 78j(b), and Rule 10b-5, 17 C.F.R. 240.10b-5. The question presented in this case may arise in both private and government actions.

STATEMENT

1. Section 10(b) of the Exchange Act makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security * * * , any manipulative or deceptive device or contrivance in contravention of"

rules promulgated by the SEC. 15 U.S.C. 78j(b). Under SEC Rule 10b-5, it is unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. 240.10b-5(b). To state a claim under Section 10(b) and Rule 10b-5, the government or a private plaintiff must allege, as relevant here, that the false statement or misleading omission was "material" and that the defendant acted with scienter. See *Stoneridge Inv. Partners, LLC* v. *Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008).

A "fundamental purpose" of the Exchange Act "was to substitute a philosophy of full disclosure for the philosophy of *caveat emptor*." *Basic Inc.* v. *Levinson*, 485 U.S. 224, 234 (1988) (quoting *SEC* v. *Capital Gains Research Bureau, Inc.*, 375 U.S. 180, 186 (1963)). Balancing "the need to insure adequate disclosure" and "the need to avoid the adverse consequences of setting too low a threshold," the Court has construed the securities laws to incorporate the "conventional tort test of materiality." *TSC Indus., Inc.* v. *Northway, Inc.*, 426 U.S. 438, 445, 449 n.10 (1976). For purposes of Section 10(b) and Rule 10b-5, an omitted fact is "material" if there is "a substantial likelihood that a reasonable shareholder would consider it important." *Basic*, 485 U.S. at 231-232 (quoting *TSC Indus.*, 426 U.S. at 449).

Liability under Section 10(b) requires proof that the defendant acted with scienter, "a mental state embracing intent to deceive, manipulate, or defraud." *Ernst & Ernst* v. *Hochfelder*, 425 U.S. 185, 193 & n.12 (1976). Under the Private Securities Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. 78u-4(b)(2), the plaintiff in a private Section 10(b) suit must plead with particularity,

inter alia, facts giving rise to a strong inference that the defendant acted with scienter. See *Tellabs, Inc.* v. *Makor Issues & Rights Ltd.*, 551 U.S. 308, 319 (2007).

2. a. Matrixx Initiatives, Inc. (Matrixx), a pharmaceutical company, sold over-the-counter cold remedies. One of its main products, Zicam Cold Remedy (Zicam), which contained zinc gluconate, was available in several forms including an intranasal gel and spray. During the period relevant to this case (October 22, 2003, to February 6, 2004), Zicam accounted for 70% of Matrixx's sales. J.A. 60a (¶ 2). Zicam, which was marketed as a homeopathic remedy, did not (and does not) have a new drug application approved by the Food and Drug Administration (FDA). J.A. 269a.[1]

b. By September 2003, three medical researchers and physicians had informed Matrixx that at least a dozen users of Zicam—including ten patients in a case study—had experienced a loss of their sense of smell, a condition known as anosmia.

In December 1999, Dr. Alan Hirsch, Neurological Director of the Smell & Taste Treatment and Research

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[1] FDA ordinarily exercises enforcement discretion to permit the marketing of homeopathic drugs without an approved new drug application under certain conditions consistent with FDA guidance. See FDA Compliance Policy Guide § 400.400, *Conditions Under Which Homeopathic Drugs May Be Marketed* (rev. Mar. 1995). That exercise of discretion, however, is not unlimited. In 2009, FDA issued a warning letter to Matrixx for marketing certain intranasal forms of Zicam without an approved new drug application in violation of 21 U.S.C. 331(d) and 355(a), stating that Zicam "may pose a serious risk to consumers" and specifically identifying reports of Zicam-associated anosmia. J.A. 268a-271a. In response, Matrixx withdrew the products at issue from the market. *Matrixx Initiatives Voluntarily Withdraws Zicam Cold Remedy Swabs, Zicam Cold Remedy Nasal Gel*, June 16, 2009, http://www.zicam.com/messagetoconsumers.

Foundation, contacted Matrixx about a possible link between Zicam and anosmia. Dr. Hirsch told Matrixx that at least one patient had developed anosmia after using Zicam in the absence of a cold, and that previous studies had demonstrated that intranasal application of zinc could be problematic. J.A. 67a-68a (¶ 25).

In September 2002, Dr. Miriam R. Linschoten of the University of Colorado spoke to Matrixx about one of her patients who had been treated for anosmia after using Zicam. Matrixx informed Dr. Linschoten that it had received complaints from others. Dr. Linschoten sent Matrixx abstracts from published studies on the link between another zinc compound (zinc sulfate) and anosmia. J.A. 68a-69a (¶¶ 26-27).

In September 2003, Matrixx learned that a third researcher, Dr. Bruce Jafek of the University of Colorado (in conjunction with Dr. Linschoten and another colleague), planned to make a poster presentation entitled "Zicam® Induced Anosmia" to the American Rhinologic Society later that month. The poster, reporting on their study involving ten patients who had developed anosmia after using Zicam, described in detail how one patient had experienced a severe burning sensation and loss of smell immediately after using Zicam. Matrixx demanded that Dr. Jafek remove the references identifying Zicam by name, and he presented the poster without such references. J.A. 69a-70a (¶¶ 28-29).

c. In an October 2003 press release and conference call, Matrixx stated that Zicam was "poised for growth in the upcoming cough and cold season"; that Zicam was the engine behind the company's "very strong momentum going into the upcoming cough and cold season"; that Matrixx was "extremely well positioned for a successful 2003/2004 cough/cold season"; and that the com-

pany expected revenues to increase by 50%. J.A. 71a-75a (¶¶ 32-34).

On November 12, 2003, Matrixx filed a Form 10-Q with the SEC. Matrixx stated that even a single unmeritorious product liability claim "could materially adversely affect our results of operations and financial condition." J.A. 75a-76a (¶ 35). Matrixx did not disclose that it had already been sued by two plaintiffs who claimed to have suffered anosmia due to Zicam use. *Ibid.*

On February 2, 2004, in response to a January 30 news report linking Zicam and anosmia (J.A. 188a-192a), Matrixx issued a press release in which it asserted that "statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading" because "the safety and efficacy of zinc gluconate" were "well established" by two clinical trials. J.A. 77a-78a (¶ 38) (quoting J.A. 193a-195a).

On February 6, 2004, the television program *Good Morning America* reported on the possible link between Zicam use and anosmia. That day, the price per share of Matrixx stock fell from $13.05 to $9.94—a single-day drop of 23.8%. J.A. 81a (¶ 43).

Also on February 6, Matrixx issued another press release reiterating that Zicam's safety had been "well established." J.A. 81a-82a (¶ 44). Later that month, however, Matrixx acknowledged (in a Form 8-K filing with the SEC) that a panel of scientists convened "to review current information on smell disorders" had concluded that "there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell." J.A. 82a (¶¶ 45-46), 206a.

By October 2004, Matrixx had been sued by approximately 284 individuals in 19 different lawsuits alleging that Zicam had caused damage to their sense of smell. Four such lawsuits (involving nine individuals) were filed before February 6, the date of the *Good Morning America* report. J.A. 87a-88a.

3. a. Respondents filed this class action under Section 10(b) and Rule 10(b)-5 on behalf of investors who had purchased Matrixx stock between October 22, 2003, and February 6, 2004. The named defendants (petitioners in this Court) were Matrixx and three of its officers. Respondents alleged, *inter alia*, that Matrixx's predictions of Zicam's commercial success were materially misleading because Matrixx had concealed a risk of anosmia that could (and did) affect Matrixx's stock price; that Matrixx's Form 10-Q filing was materially misleading because it failed to disclose a pending lawsuit claiming that Zicam caused anosmia; and that Matrixx's statements about scientific evidence establishing Zicam's safety were materially misleading because, as Matrixx later acknowledged, there was insufficient evidence to make that determination. J.A. 58a-111a.

b. The district court dismissed respondents' complaint. Pet. App. 35a-54a. Citing *In re Carter-Wallace, Inc.*, 220 F.3d 36 (2d Cir. 1998), the district court stated that "adverse information related to the safety of a product is not material unless such reports provide reliable statistically significant information that a drug is unsafe." Pet. App. 45a. The court found that "12 user complaints is not statistically significant" and that respondents had therefore "failed to present evidence of a statistically significant correlation between the use of Zicam and anosmia." *Id.* at 50a. The district court further ruled that respondents' allegations of scienter

failed to satisfy the PSLRA's heightened pleading standard. *Id.* at 50a-54a.

4. The court of appeals reversed and remanded. Pet. App. 1a-34a.

a. The court of appeals held "that the district court erred in relying on the statistical significance standard to conclude that [respondents] failed adequately to allege materiality." Pet. App. 23a. The court explained that "[a]n omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important," *id.* at 21a-22a (quoting *TSC Indus.*, 426 U.S. at 449), and it noted this Court's rejection of bright-line materiality rules in *Basic*, *id.* at 23a. The court of appeals reasoned that by using the "statistical significance" standard, the district court had "made a decision that should have been left to the trier of fact." *Id.* at 24a. After "engag[ing] in the fact-specific inquiry required by *Basic*," and in light of all the allegations in the complaint, the court of appeals concluded that the respondents had "sufficiently alleged materiality." *Id.* at 24a-26a.

b. The court of appeals also rejected the district court's determination that respondents had failed adequately to allege scienter. Pet. App. 26a-34a. The court explained that at the time Matrixx had "touted the potential for growth and profitability of Zicam" and alerted investors generally to the risks of litigation, Matrixx (1) knew that at least a dozen Zicam users had developed anosmia, (2) was aware that past studies linked another zinc compound to anosmia, (3) had prevented Dr. Jafek from using Zicam's name in a research presentation, and (4) was defending itself in an anosmia-related lawsuit. *Id.* at 32a. Moreover, the court noted, Matrixx had represented that clinical trials had estab-

lished the safety of Zicam even "though it was subsequently reported that Matrixx had not conducted such studies." *Id.* at 32a-33a. Based on those allegations, the court concluded that "the inference of scienter is 'cogent and at least as compelling' as any 'plausible non-culpable explanation' for [petitioners'] conduct," and that respondents therefore satisfied the PSLRA's standard for pleading scienter. *Id.* at 33a-34a (quoting *Tellabs*, 551 U.S. at 324).

SUMMARY OF ARGUMENT

A. Materiality is a touchstone of liability under Section 10(b) and Rule 10b-5, and this Court has held that an omitted fact is "material" when there is a substantial likelihood that a reasonable investor would have considered it important. *Basic Inc.* v. *Levinson*, 485 U.S. 224, 231-232 (1988). Petitioners propose to depart from that settled understanding in favor of a categorical rule that deems information about an adverse effect associated with use of a drug immaterial unless the association is statistically significant.

1. That rule conflicts with *Basic*'s standard for two important reasons. First, evidence other than data showing a statistically significant association can suggest a causal link between use of a drug and an adverse effect. Medical researchers, courts, and FDA regularly consider multiple factors in assessing causation, especially where (as here) the available epidemiological data are inconclusive. Second, a reasonable investor may consider information suggesting an adverse drug effect important even if it does not prove that the drug causes the effect. Even reports that simply suggest causation may affect the behavior of consumers, potential litigants, and FDA. Because such reactions can affect a

product's commercial viability, and thus the company's financial condition, a reasonable investor often will want to know about such information.

2. Petitioners' proposed rule also conflicts with this Court's precedents because it establishes a rigid restriction, particularly at the pleading stage. This Court previously rejected a "bright-line" rule both because it was too underinclusive and because the materiality inquiry requires "delicate assessments" better suited to the trier of fact. *Basic*, 485 U.S. at 236; *TSC Indus., Inc.* v. *Northway, Inc.*, 426 U.S. 438, 450 (1976). Even in product-liability cases, where causation is an element, courts look beyond statistical significance, and petitioners cite no case that was dismissed for lack of statistical significance at the pleading stage.

3. The inquiry described in *Basic* provides adequate guidance to courts and companies. In *Basic*, this Court rejected the same policy argument that petitioners advance here, *i.e.*, that their bright-line rule is necessary to avoid inundating the market with irrelevant disclosures. 485 U.S. at 234. That argument is particularly unpersuasive here in light of FDA-reporting requirements for drug companies and FDA's policy of making adverse event data publicly available. As this Court explained, courts can look to several illustrative factors to determine whether allegations of materiality are sufficient to survive a motion to dismiss in this context. Doing so will screen out unmeritorious claims.

4. Respondents' complaint adequately alleges materiality. First, the source of most of the adverse information was not random users but experts in the field, based on their clinical observation of at least a dozen cases of anosmia in Zicam users and published studies establishing a link between anosmia and another zinc compound.

Second, drug-induced anosmia is a serious side effect, especially relative to any benefit provided by Zicam. Third, Zicam did not undergo pre-market evaluation by FDA and was marketed without FDA approval. Fourth, the temporal relationship between Zicam use and anosmia, its intranasal application, and the prior zinc studies suggest a plausible link. Fifth, Zicam, which accounted for 70% of Matrixx's sales at the time, was crucial to Matrixx's success, as confirmed by the 23.8% drop in stock price on the day the information was disclosed.

B. For similar reasons, a plaintiff need not allege statistical significance in order to plead scienter. The PSLRA requires a private Section 10(b) plaintiff to plead with particularity facts showing a "strong inference" of scienter, 15 U.S.C. 78u-4(b)(2), *i.e.*, an inference "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007). The facts alleged in respondents' complaint, including Matrixx's intervention to stop Dr. Jafek from using Zicam's name in an academic presentation and its misrepresentations and omissions regarding a pending product-liability lawsuit and Zicam's "well established" safety, satisfy that standard.

ARGUMENT

RESPONDENTS HAVE ADEQUATELY PLEADED THAT PETITIONERS' PUBLIC STATEMENTS CONTAINED MATERIAL OMISSIONS AND THAT PETITIONERS ACTED WITH SCIENTER

A. Information Suggesting That A Drug Causes An Adverse Effect May Be "Material" To Investors Even Absent Statistical Significance

Under this Court's precedents, an omitted fact is "material" for securities-fraud purposes if 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 available." *Basic Inc.* v. *Levinson*, 485 U.S. 224, 231-232 (1988) (quoting *TSC Indus., Inc.* v. *Northway, Inc.*, 426 U.S. 438, 449 (1976)). That inquiry generally 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," and those assessments are "peculiarly ones for the trier of fact." *TSC Indus., Inc.*, 426 U.S. at 450.

Petitioners urge this Court to bypass that contextual inquiry altogether in cases where a Section 10(b) claim is premised on a company's failure to disclose information about adverse effects associated with use of its drug. Petitioners would replace the nuanced approach described above with a categorical rule that such information is immaterial unless a "statistically significant" association is alleged. As this case indicates, however, information suggesting a causal link between use of a drug and a serious adverse effect may significantly alter the behavior of consumers, regulators, and product-liability plaintiffs, even when there is no allegation of a

statistically significant association. Because those reactions can affect a company's financial well-being, and its share price, reasonable investors would consider such information to be highly relevant to their investment decisions. Under the approach described in *Basic*, respondents adequately alleged that petitioners' public statements contained material omissions.

1. Reasonable investors or potential investors in a drug company may be concerned about information that raises concerns about the safety of the company's products, even when that information does not establish a "statistically significant" association

Petitioners contend (1) that proof of a statistically significant association is the only "scientifically reliable basis for inferring a causal link between the product use and the [adverse] event," and (2) that a reasonable investor would consider information suggesting a potential link between a drug and an adverse event to be important only if such proof existed. Pet. Br. 13-14, 15-16. Both of those contentions are incorrect.

First, data showing a statistically significant association are not essential to establish a link between use of a drug and an adverse effect. As petitioners ultimately acknowledge (Br. 44 n.22), medical researchers, regulators, and courts consider multiple factors in assessing causation. Second, information suggesting an adverse drug effect may be important to a reasonable investor even if it does not prove that a causal link exists. Such information may affect the behavior of consumers and potential litigants, and FDA can and does take regulatory action without evidence establishing statistical significance. Because those responses affect a product's commercial viability, and thus the company's financial

condition, a reasonable investor often will want to know about such information.

a. Statistical significance is a limited and non-exclusive tool for inferring causation

Statistical significance is not synonymous with practical significance. Statistical significance is a measure of whether data indicate that two variables "occur together more frequently than one would expect by chance." Michael D. Green, Michael Freedman & Leon Gordis, *Reference Guide on Epidemiology*, in *Reference Manual on Scientific Evidence* 333, 348, 354 (2d ed. 2000) (*Reference Guide on Epidemiology*). For any association between a drug and a harm observed in a sample, there are many possible explanations for why the subjects that used the drug had a higher incidence of harm than those that did not. One explanation is that the drug causes the harm, but other potential explanations, including chance, exist. Statistical significance speaks solely to the probability that chance explains an observed association. Richard Lempert, *The Significance of Statistical Significance*, 34 Law & Soc. Inquiry 225, 232 (2009) (Lempert).

To assess statistical significance in the medical context, a researcher begins with the "null hypothesis," *i.e.*, that there is no relationship between the drug and the adverse effect. The researcher calculates a "p-value," which is the probability that the association observed in the study would have occurred even if there were in fact no link between the drug and the adverse effect. If that p-value is lower than the "significance level" selected for the study, then the results can be deemed statistically significant.

The significance level most commonly used in medical studies is 0.05. If the p-value is less than 0.05, there is less than a 5% chance that the observed association between the drug and the effect would have occurred randomly, and the results from such a study are deemed statistically significant. Conversely, if the p-value is greater than 0.05, there is greater than a 5% chance that the observed association would have occurred randomly, and the results are deemed not statistically significant. See *Reference Guide on Epidemiology* 357-358; David Kaye & David A. Freedman, *Reference Guide on Statistics*, in *Reference Manual on Scientific Evidence* 123, 123-125 (2d ed. 2000) (*Reference Guide on Statistics*).

While statistical significance provides some indication about the validity of a correlation between a product and a harm, a determination that certain data are not statistically significant—let alone, as here, the absence of any determination one way or the other—does not refute an inference of causation. See Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation*: *The Legacy of Agent Orange and Bendectin Litigation*, 86 Nw. U. L. Rev. 643, 682-683 (1992). Take, for example, results from a study, with a p-value of 0.06, showing that those who take a drug develop a rare but serious adverse effect (*e.g.*, permanent paralysis) three times as often as those who do not. Because the p-value exceeds 5%, the study's results would not be considered statistically significant at the 0.05 level. But since the results indicate a 94% likelihood that the observed association between the drug and the effect would *not* have occurred randomly, the data would clearly bear on the drug's safety. Upon release of such a study, "confidence in the safety of the drug in question should diminish, and if the drug were impor-

tant enough to [the issuer's] balance sheet, the price of its stock would be expected to decline." Lempert 239.[2]

The observed association may not be statistically significant for reasons other than the lack of a causal connection, including sample size and methodology. See *Reference Guide on Statistics* 122-126. In some circumstances—*e.g.*, where an adverse effect is subtle or has a low rate of incidence—an inability to obtain a data set of appropriate quality or quantity may preclude a finding of statistical significance. *Ibid.* That does not mean, however, that researchers have no basis on which to infer a plausible causal link between a drug and an adverse effect.

More broadly, causation can appropriately be inferred through consideration of multiple factors independent of statistical significance. In a footnote, petitioners acknowledge that critical fact:

> [C]ourts permit an inference of causation on the basis of scientifically reliable evidence other than statistically significant epidemiological data. In such cases experts rely on a lengthy list of factors to draw reliable inferences, including, for example, (1) the "strength" of the association, including "whether it is statistically significant"; (2) temporal relationship between exposure and the adverse event; (3) consis-

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[2] The same principle applies to studies suggesting that a particular drug is efficacious. A study in which the cure rate for cancer patients who took a drug was twice the cure rate for those who took a placebo could generate meaningful interest even if the results were not statistically significant. See Jonathan A.C. Sterne & George Davey Smith, *Sifting the evidence - what's wrong with significance tests?*, 322 British Med. J. 226, 227 (2001) (overemphasis on statistical significance may cause "clinically important differences" to be incorrectly "denoted as non-significant and ignored").

> tency across multiple studies; (4) "biological plausibility"; (5) "consideration of alternative explanations" (i.e., confounding); (6) "specificity" (i.e., whether the *specific* chemical is associated with the *specific* disease at issue); and (7) dose-response relationship (i.e., whether an increase in exposure yields an increase in risk).

Pet. Br. 44 n.22 (citations omitted). Those and other factors for inferring causation have been well recognized in the medical literature and by the courts of appeals. See, *e.g.*, *Reference Guide on Epidemiology* 345-347 (discussing relevance of toxicologic studies), 375-379 (citing, *e.g.*, Austin Bradford Hill, *The Environment and Disease: Association or Causation*?, 58 Proc. Royal Soc'y Med. 295 (1965)); *Best* v. *Lowe's Home Centers, Inc.*, 563 F.3d 171, 178 (6th Cir. 2009) ("an 'overwhelming majority of the courts of appeals' agree" that differential diagnosis, a process for medical diagnosis that does not entail statistical significance tests, informs causation) (quoting *Westberry* v. *Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999)); *Ferebee* v. *Chevron Chem. Co.*, 736 F.2d 1529, 1536 (D.C. Cir.) ("[P]roducts liability law does not preclude recovery until a 'statistically significant' number of people have been injured."), cert. denied, 469 U.S. 1062 (1984). As discussed below (see pp. 19-20, *infra*), FDA relies on a number of those factors in deciding whether to take regulatory action based on reports of an adverse drug effect.

That criteria other than statistical significance are used to infer causation exposes the dramatic underinclusiveness of petitioners' proposed materiality standard. Petitioners contend (Br. 45 n.22) that "[t]his case does not present the question whether a securities fraud case can be premised on nondisclosure of information

establishing a causal inference on the basis of [the additional] criteria" described above. That is incorrect. As discussed below (see pp. 30-31, *infra*), respondents' complaint alleges facts that were known to Matrixx during the relevant time period and that suggest a potential causal link between Zicam use and anosmia.

b. Information suggesting a possible link between a drug and an adverse effect may alter the behavior of consumers, regulators, and potential product-liability plaintiffs, even absent statistically significant evidence of causation

"[T]he role of the materiality requirement" in a securities-fraud case is "to filter out essentially useless information that a reasonable investor would not consider significant." *Basic*, 485 U.S. at 234. As indicated by their reliance on product-liability cases (Br. 23-25, 37-39), petitioners conflate that materiality standard with the more demanding requirement applicable in a product-liability suit, *i.e.*, that the plaintiff prove that the allegedly defective product more likely than not caused the injury.[3]

Information suggesting that a company's product causes harm may be important to an investor even if the information does not establish that the causal link more likely than not exists. A reasonable investor cares about the impact undisclosed information will have on the company's finances and stock price. The extent of that impact depends on the conduct of consumers, regulators, and possible tort plaintiffs. Because those actors may respond in ways that hurt the company based on information that suggests but does not prove that the com-

[3] As noted above (pp. 15-16, *supra*), even causation in a product-liability claim may be proven without statistical significance.

pany's product causes a particular harm, there are many reasons why an investor would want to be alerted to the existence of such information.

First, reasonable consumers may decline to buy products that they perceive as risky, even though the available evidence does not suggest that it is "more likely than not" that the product causes harm. That is particularly true when the possible adverse effect is relatively serious and the benefit associated with the product is modest and/or available from a competing product. For example, publicity about children born with physical deformities after their mothers took an anti-nausea drug (Bendectin) sharply diminished the drug's sales despite FDA's contemporaneous finding that no causal link existed. The company, which at one point sold three million doses annually, eventually stopped making the drug. See *Company Stops Making Morning Sickness Drug*, N.Y. Times, June 10, 1983, at A16 (*Company Stops Making Drug*).[4] Under petitioners' proposed rule, however, a company that concealed information concerning such adverse events—or even a company that falsely stated that no such events had occurred (see pp. 24-25, *infra*)—would be immune from Section 10(b) liability.

Second, reports of serious adverse events often attract regulatory attention even absent statistically significant evidence of causation. Such regulatory attention can have a significant impact on a drug's commercial success and litigation risk. Petitioners understate

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[4] This phenomenon is not limited to the health product context. Audi's sales dropped more than 80% in the five-year period following a *60 Minutes* segment suggesting that Audi vehicles accelerated without warning, even though those claims were never proven true. Joseph P. White & Dionne Searcey, *Audi Case Set Template for Toyota's Troubles*, Wall. St. J., Mar. 12, 2010, at B1.

the importance of adverse event reports by emphasizing their limitations without explaining the manner in which FDA actually uses such reports.

Adverse event reporting is a critical element of FDA's post-market surveillance program. FDA receives these reports directly from health-care professionals, researchers, consumers, and others (*e.g.*, family members and lawyers), as well as from manufacturers (which generally must forward them to FDA subject to mandatory reporting rules, see p. 26, *infra*). FDA employs a multi-disciplinary staff of safety evaluators, epidemiologists, and other scientists to review adverse event data by a variety of methods, including the application of computer algorithms as well as scrutiny of individual reports. When the review identifies a "safety signal"—often in the form of a serious, rare, and/or unexpected adverse event—FDA further investigates the drug and its link to that event. See FDA, *The Clinical Impact of Adverse Event Reporting* 6-7 (1996), http://www.fda.gov/downloads/ Safety/MedWatch/UCM168505.pdf (*Adverse Event Reporting*).

As petitioners acknowledge (Br. 23), FDA does not apply any single metric for determining when additional inquiry or action is necessary, and it certainly does not insist upon "statistical significance." See *Adverse Event Reporting* 7. Indeed, statistical significance is not a scientifically appropriate or meaningful standard in evaluating adverse event data outside of carefully designed studies. *Id.* at 5; cf. Lempert 240 ("it is meaningless to talk about receiving a statistically significant number" of complaints). Rather, in exercising its scientific judgment based on the facts and circumstances of each case, FDA relies on a range of factors including: (1) strength of the association; (2) temporal relationship;

(3) consistency across data sources; (4) dose-response effect; (5) biologic plausibility; (6) seriousness of event relative to disease being treated; (7) potential to mitigate risk in the population; (8) feasibility of observational or clinical study designs; and (9) benefit the product provides, including availability of other therapies. FDA, *Guidance for Industry: Good Pharmacovigilance Practices and Pharmaceoepidemiologic Assessment* 18 (2005), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071696.pdf (*Good Pharmacovigilance Practices*).

Based on its analysis, FDA may take an array of regulatory actions—*e.g.*, issuing a warning letter, revising product labeling, communicating new safety information to the public, and removing the product from the market. See FDA, *Adverse Event Reporting System (AERS)*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/adversedrugeffects/default.htm. By way of example, in June 2009, FDA issued a warning letter to Matrixx. J.A. 267a-274a. Among other violations, FDA stated that Zicam was misbranded because its labeling lacked "adequate warnings regarding the risk of anosmia." J.A. 271a (citing 21 U.S.C. 321(n) (taking into account whether the labeling omits "material" facts)). FDA did not cite statistically significant evidence of an association between Zicam and anosmia. Rather, FDA cited its receipt of more than 130 reports of anosmia associated with Zicam use; the relative paucity of such reports for other widely-used intranasal cold products; and the scientific literature analyzing the effect of zinc on olfactory function. J.A. 270a. Despite petitioners' characterization of adverse event reports as "inherently unreliable"

(Br. 20, 29), FDA thus takes a much more nuanced, context-specific approach.

FDA's reliance on adverse event reports as bases for regulatory action has significant practical consequences for marketing of the targeted product. In its November 2003 Form 10-Q filing, Matrixx identified as a risk factor that "FDA and other government regulation may restrict our ability to sell our products." J.A. 175a. And in response to the FDA warning letter issued in June 2009, Matrixx withdrew altogether the intranasal forms of Zicam from the market. See note 1, *supra*.

Third, when users of a drug experience an adverse event, a company may face product-liability litigation and incur related expenses, even if reliable proof of causation is lacking. These expenses include the direct costs of defending against claims (including experts, discovery, and attorney's fees) and paying settlements and judgments, as well as the indirect costs of harm to product reputation and higher insurance rates. See, *e.g.*, *Company Stops Making Drug*, *supra* (citing rising insurance premiums and cost of defending product-liability lawsuits); Gardiner Harris, *FDA Warns Against Use of Popular Cold Remedy*, N.Y. Times, at A14 (June 17, 2009) (noting that Matrixx settled some anosmia-based lawsuits for $12 million in 2006). Indeed, in its Form 10-Q filing, Matrixx acknowledged that even meritless product-liability suits could harm the company financially. J.A. 178a. A reasonable investor would therefore attach significance to information bearing on the likelihood that such suits might be filed.

2. A statistical significance test for materiality conflicts with this Court's decision in* Basic *and is particularly problematic at the pleading stage

Because petitioners' rigid "statistical significance" requirement does not capture information to which a reasonable investor would attach importance (Part A.1, *supra*), it contravenes this Court's analysis of materiality in securities-fraud cases. In *Basic*, the Court rejected a proposed standard under which the existence of preliminary merger discussions would be treated as material only when the merger partners had reached "agreement in principle" on a price and structure for the transaction. 485 U.S. at 232-236. The Court explained that, while such a "bright-line" rule is "easier to follow than a standard that requires the exercise of judgment in light of all the circumstances," "[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. This Court noted that courts "would do well to heed th[e] advice" of the Advisory Committee on Corporate Disclosure that materiality is "judgmental in nature and it is not possible to translate this into a numerical formula." *Ibid.* (quoting *Report of the Advisory Committee on Corporate Disclosure to the SEC*, 95th Cong., 1st Sess. 327 (1977)).[5]

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[5] In any event, petitioners are wrong in suggesting that a "statistical significance" standard would eliminate difficulties of administration. Statistical significance is a function of research design, which in turn is a function of various choices and assumptions about which qualified experts can and do frequently disagree. See *International Bhd. of Teamsters* v. *United States*, 431 U.S. 324, 340 (1977) (statistics "come in infinite variety," and "their usefulness depends on all of the surrounding facts and circumstances"). Statistical signficance does not resolve certain methodological concerns, such as "bias" in the selection of study subjects or "confounding variables." *Reference Guide on Epidemiology* 363-373. Petitioners do not commit to a specific significance level, and they suggest that drug companies should be permitted

Petitioners' proposed statistical significance rule would have the very same defects that this Court identified in *Basic*, and is even more problematic because it would mandate dismissal of suits *at the pleading stage*. A determination of materiality generally "requires delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts," and such "assessments are peculiarly ones for the trier of fact." *TSC Indus.*, 426 U.S. at 450. Dismissal of a Section 10(b) claim on materiality grounds is therefore appropriate only when the alleged omissions "are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *ECA* v. *J.P. Morgan Chase Co.*, 553 F.3d 187, 197 (2d Cir. 2009).

Under petitioners' proposed rule (Br. 48), a plaintiff must at least allege facts establishing that the rate of reported adverse events exceeds the background rate of incidence "by a statistically significant degree." As explained above (see p. 19, *supra*), however, adverse event reports do not lend themselves to a statistical-significance analysis. At a minimum, the standard petitioners advocate would require the design of a scientific study able to capture the relative rates of incidence (either through a clinical trial or observational study); enough participants and data to perform such a study and make it powerful enough to detect any increased incidence of the adverse effect; and a researcher equipped and interested enough to conduct it. Nothing in this Court's decisions suggests that respondents must undertake that

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to challenge the premises underlying an allegation of statistical significance. Pet. Br. 33 n.15 (arguing that statistically significant evidence is "not *necessarily* material" because "the underlying data may be flawed"), 35-36.

"difficult, time-consuming, and expensive" process, *Reference Guide on Epidemiology* 346, to demonstrate that reasonable investors would have attached significance to information casting doubt on Zicam's safety. And it would be particularly inappropriate to impose that burden at the pleading stage, especially where, as here, the drug company possesses pertinent information that plaintiffs and researchers might be unable to access without discovery. See J.A. 272a (noting Matrixx's possession of 800 reports apparently not disclosed to FDA); Pet. Br. 18-19 (asserting that company was not required during the class period to report adverse Zicam-related events to FDA).

Plaintiffs in other contexts are not subject to comparable pleading requirements. Petitioners cite dozens of cases from various areas of the law (Br. 38-42)—including products liability, employment discrimination, jury selection, and voting rights—but they identify not a single case that was dismissed at the pleading stage for failure to allege statistical significance. Indeed, as noted above (pp. 15-16, *supra*), courts do not view the lack of statistically significant evidence as dispositive even at later stages of litigation. Rather, statistical significance is simply one of many factors considered in deciding whether an expert's testimony is admissible or whether scientific evidence is sufficient to support a finding of causation.

Moreover, although this case involves principally the *nondisclosure* of information that was potentially relevant to respondents' investment decisions, petitioners' proposed materiality standard would apply equally to affirmative misrepresentations about facts bearing on the safety of drugs and other consumer products. For a securities-fraud claim, the false or misleading nature

of a statement (or omission) is not enough, without materiality, to trigger liability. See *Basic*, 485 U.S. at 238 ("[I]t is not enough that a statement is false or incomplete, if the misrepresented fact is otherwise insignificant."). Under petitioners' view, facts about adverse drug effects are *per se* immaterial absent statistically significant data. "[B]y definition, then, information concerning [such facts] could be withheld *or even misrepresented* without a violation of Rule 10b-5." *Id.* at 233 (emphasis added). Under that approach, a company that received credible reports of a rare but serious adverse effect associated with use of its drug could falsely represent that it was unaware of any such complaints, and nevertheless obtain dismissal of a Section 10(b) suit filed against it, unless the reports were substantiated by evidence of a statistically significant association.

3. **Basic*'s materiality inquiry does not result in over-disclosure and appropriately filters out unmeritorious claims***

Petitioners' primary policy-based defense of their proposed statistical significance standard is that companies would otherwise be compelled to disclose all reports of adverse events, inundating the market with useless or suspect information and thereby undermining reasoned investment decisionmaking. Pet. Br. 26-32. This Court "soundly rejected" a comparable rationale for the "bright-line" rule proposed in *Basic*. 485 U.S. at 234. The Court explained that "[d]isclosure, and not paternalistic withholding of accurate information, is the policy chosen and expressed by Congress." *Ibid.* Rather than "assume[] that investors are nitwits, unable to appreciate—even when told—that" adverse event reports by themselves do not establish a conclusive causal link,

courts should trust investors to make informed decisions. *Ibid.* (citation omitted).

Petitioners' concern that indiscriminate release of adverse event reports will mislead investors is particularly unpersuasive in light of statutory and regulatory requirements that drug manufacturers report those events to FDA, and FDA's policy of making those reports publicly available. For all drugs with an approved new drug application as well as for prescription drugs without an approved new drug application, FDA has long required companies to report post-marketing "adverse drug experiences." 21 C.F.R. 314.80, 310.305. In 2006, Congress required manufacturers of non-prescription drugs without approved new drug applications to submit reports of "serious adverse events." 21 U.S.C. 379aa. And since 1998, FDA has made the raw adverse event data publicly available in electronic files (initially through the National Technical Information Service, a government clearinghouse, and, since 2004, through the FDA's own website). Petitioners' contention that such reports are more likely to mislead than to inform the public is thus directly contrary to FDA's considered judgment.[6]

In any event, affirmance of the court of appeals' judgment would not mean that drug companies must

[6] Because Zicam was a non-prescription drug marketed without an approved new drug application, it was not subject to any of the aforementioned FDA-reporting requirements during the class period (which predated Section 379aa's enactment). See Pet. Br. 18-19. In circumstances where adverse event reports have been submitted to FDA and then made available to the public, however, the drug companies involved could be expected to defend against a fraud-by-omission claim by arguing that the adverse information has already been disseminated to the market via FDA. See, *e.g.*, Pharmaceutical Research & Manufacturers of Am. Amicus Br. 16-17 & n.5.

disclose to investors every isolated report of an adverse event. As an initial matter, the securities laws require disclosure only in limited situations. In particular, a drug company can choose simply to remain silent about the safety and prospects of its product and avoid any obligation to disclose potentially conflicting information. See *Basic*, 485 U.S. at 239 n.17 ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5."). A duty to disclose arises only when a company chooses to make affirmative representations, including predictive statements about product success and safety, that are incomplete and misleading without omitted information. See 17 C.F.R. 240.10b-5(b) (making it unlawful "to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading"); see also, *e.g.*, *Helwig* v. *Vencor*, 251 F.3d 540, 561 (6th Cir. 2001) ("With regard to future events, uncertain figures, and other soft information, a company may choose silence or speech elaborated by the factual basis as then known—but it may not choose half-truths.").

Even when a company has spoken, it need not indiscriminately release all conceivably relevant information in order to avoid potential Section 10(b) liability. In *Basic*, after rejecting the proposed "bright-line" rule, this Court sought to guide courts' application of the "reasonable investor" materiality standard to speculative information or events. "Under such circumstances," the Court explained, "materiality 'will depend at any given time upon a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity.'" *Basic*, 485 U.S. at 238 (quoting *SEC* v. *Texas Gulf Sulphur Co.*, 401 F.2d 833, 849 (2d Cir. 1968) (en banc),

cert. denied, 394 U.S. 976 (1969)). While noting the fact-dependent nature of that inquiry, the Court identified several factors (in a non-exhaustive fashion) that might be relevant in the merger context that was at issue in *Basic*. *Id.* at 239.

As it did in *Basic*, this Court should accord "due deference" to the SEC's views, as conveyed in this brief, on the proper materiality inquiry. 485 U.S. at 239 n.16. In this context, involving similarly uncertain information about potential adverse effects of using a company's drug, materiality may depend on multiple factors. With respect to the likelihood that the adverse-effect information will affect the drug's prospects, a court can consider the source of the reported adverse event (*Good Pharmacovigilance Practices* 4-5); the rate and severity of the adverse event; the potential benefit the drug provides; the availability of alternate therapies; whether the drug is new and has received FDA approval after clinical investigation (*Carter-Wallace*, 220 F.3d at 42); and the plausibility of a causal link (based on many of the factors FDA considers, see pp. 19-20, *supra*, such as temporal relationship and prior studies). With respect to the importance of the drug's success to the company's overall financial outlook, a court can consider the proportion of the company's current and expected revenues/profits from the drug, as well as the extent of any drop in stock price following disclosure of the omitted information. See, *e.g.*, *Hillson Partners, Ltd.* v. *Adage, Inc.*, 42 F.3d 204, 219 (4th Cir. 1994) (deeming omissions immaterial where financial impact on company would be negligible if prediction did not come true); *Ganino* v. *Citizens Util. Co.*, 228 F.3d 154, 162-63, 67 (2d Cir. 2000) (taking into account market movement upon disclosure along with other indicia). These factors are only illustrative, and

"[n]o particular event or factor * * * need be either necessary or sufficient by itself to render [such information] material." *Basic*, 485 U.S. at 239.

Application of *Basic*'s materiality standard in light of the aforementioned factors therefore would sometimes permit a company to withhold adverse drug information. For example, a company could reasonably conclude that a single report of an adverse event from an anonymous user, or a dozen reports of a dozen different adverse events, would not be important to a reasonable investor for a widely used drug that had undergone rigorous premarket testing and FDA review and approval. Even if the reports of an adverse effect were more numerous or reliable, a company could reasonably conclude that they were not material if the effect was minor and transient relative to the drug's benefit and the drug sales did not contribute meaningfully to the company's revenues. The choice that petitioners offer the Court—adopt a statistical significance threshold or force companies to disclose every report of an adverse effect to stave off liability—is ultimately a false one.[7]

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[7] The PSLRA's provisions governing private actions, including the heightened pleading requirements for misleading statements and omissions (15 U.S.C. 78u-4(b)(1)), and the safe harbor for forward-looking statements (15 U.S.C. 78u-5), establish additional mechanisms for weeding out meritless private securities-fraud lawsuits without unnecessarily impinging on the government's enforcement efforts. Moreover, under the judicially crafted "bespeaks caution" doctrine, predictive statements are not actionable if they are accompanied by specific cautionary language. *E.g.*, *Edward J. Goodman Life Income Trust* v. *Jabil Circuit, Inc.*, 594 F.3d 783, 796 (11th Cir. 2010). These protections provide further filtering above and beyond *Basic*.

4. Respondents' allegations regarding the omitted information about Zicam use and anosmia are sufficient to plead materiality under Basic

Applying *Basic*'s standard in light of the factors discussed above, respondents' complaint adequately alleges materiality.

First, much of the information associating Zicam use with anosmia was provided by experts in the field. Three different medical researchers and physicians communicated their concerns about a link between Zicam use and anosmia. As conveyed to Matrixx, those concerns were based in part on the experts' treatment and observation of at least a dozen patients who experienced anosmia after using Zicam, and in part on published studies establishing a link between anosmia and another zinc compound.

Second, drug-induced anosmia is a relatively serious side effect. J.A. 274a n.2. Given that Zicam is a medication that claims to lessen the duration of cold symptoms and that many alternate remedies are available, consumer awareness of even a low probability of developing anosmia could have significantly reduced Zicam's sales.

Third, Zicam did not have a new drug application approved by FDA. J.A. 269a. Clinical trials sufficient for FDA approval can take years to complete, may involve thousands of human subjects, and systematically evaluate a drug's benefits and risks. See, *e.g.*, *Abigail Alliance* v. *Von Eschenbach*, 495 F.3d 695, 697-698 (D.C. Cir. 2007), cert. denied, 128 S. Ct. 1069 (2008). A reasonable investor could attach greater significance to adverse event reports concerning a new drug (like Zicam) that has not undergone FDA review and ap-

proval than to similar reports concerning a drug for which a larger body of data was available.[8]

Fourth, several of the facts alleged—independent of the expert assessments shared with Matrixx—suggest a plausible causal link between Zicam use and anosmia. According to the complaint, at least some users suffered a severe burning sensation and loss of smell immediately after intranasal application of Zicam. J.A. 69a-70a (¶ 28). Those allegations, combined with the published studies linking anosmia to another zinc compound, support the notion that consumers (and possibly regulators) would consider a causal connection plausible.

Fifth, the fact that Matrixx's stock fell 23.8% the day after the *Good Morning America* story supports the conclusion that the omitted information would have been important to a reasonable investor. J.A. 81a (¶ 43). The strong correlation between Zicam's success and Matrixx's financial prospects is unsurprising given that Zicam constituted 70% of Matrixx's total sales at the time. J.A. 60a (¶ 2). Under petitioners' extreme view, by contrast, a trier of fact would not even be allowed to consider whether a reasonable investor would have attached significance to information that, when released to the public, demonstrably affected actual investor behavior.

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[8] Citing a press release, petitioners state that "[p]rior to the events at issue here, Matrixx conducted two published double-blind, placebo-controlled, randomized clinical studies of the intranasal application of zinc gluconate." Pet. Br. 5 (citing J.A. 193a-194a). Matrixx effectively contradicted that press release (and undercut the probative value of those two studies), however, when it subsequently declared that a panel of scientists convened "to review current information on smell disorders" had concluded that "there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell." J.A. 82a (¶¶ 45-46).

B. Respondents Adequately Alleged That Petitioners Acted With Scienter

The PSLRA requires a private plaintiff in a Section 10(b) suit to "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). Scienter, the state of mind required under Section 10(b), is "a mental state embracing intent to deceive, manipulate, or defraud." *Ernst & Ernst* v. *Hochfelder*, 425 U.S. 185, 193 n.12 (1976). "Every Court of Appeals that has considered the issue has held" that scienter may be proven "by showing that the defendant acted intentionally or recklessly." *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308, 318 n.3 (2007). A "strong inference" of scienter is an inference "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 314.

Respondents satisfied the PSLRA standard. In addition to the facts discussed above (pp. 30-31, *supra*), Matrixx prevented Dr. Jafek from using Zicam's name in the presentation of his case study on anosmia, suggesting strongly that Matrixx was aware of the potential damage that such a disclosure could do to Zicam's prospects. Matrixx's failure to disclose a pending anosmia-related lawsuit while noting the material risks of even a meritless product-liability claim further suggests deceptive intent. J.A. 75a-76a (¶ 35). Finally, although Matrixx publicly stated that reports of anosmia were "completely unfounded" because "the safety and efficacy of zinc gluconate" were "well established," J.A. 77a-78a (¶ 38), it shortly thereafter admitted that a panel of scientists it had convened had concluded that "there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a

person's ability to smell," J.A. 82a (¶¶ 45-46). Taken together, the facts alleged in respondents' complaint establish the requisite "strong inference that the defendant acted with the required state of mind." 15 U.S.C. 78u-4(b)(2).

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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NOVEMBER 2010

APPENDIX

1. 15 U.S.C. 78j provides in pertinent part:

Manipulative and deceptive devices

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange—

* * * * *

(b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement (as defined in section 206B of the Gramm-Leach-Bliley Act), 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.

2. 15 U.S.C. 78u-4 provides in pertinent part:

Private securities litigation

* * * * *

(b) Requirements for securities fraud actions

(1) Misleading statements and omissions

In any private action arising under this chapter in which the plaintiff alleges that the defendant—

(A) made an untrue statement of a material fact; or

(B) omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading;

the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

(2) Required state of mind

In any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.

3. 17 C.F.R. § 240.10b-5 provides:

Employment of manipulative and deceptive devices.

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,

(a) To employ any device, scheme, or artifice to defraud,

(b) To 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, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,

in connection with the purchase or sale of any security.