No. 09-

IN THE

Supreme Court of the United States

MATRIXX INITIATIVES INC., ET AL.,
Petitioners,

v.

JAMES SIRACUSANO AND NECA-IBEW PENSION FUND,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Respondents filed suit under § 10(b) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b-5, alleging that petitioners committed securities fraud by failing to disclose "adverse event" reports—i.e., reports by users of a drug that they experienced an adverse event after using the drug. The First, Second, and Third Circuits have held that drug companies have no duty to disclose adverse event reports until the reports provide statistically significant evidence that the adverse events may be caused by, and are not simply randomly associated with, a drug's use. Expressly disagreeing with those decisions, the Ninth Circuit below rejected a statistical significance standard and allowed the case to proceed despite the lack of any allegation that the undisclosed adverse event reports were statistically significant. The question presented is:

Whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 based on a pharmaceutical company's nondisclosure of adverse event reports even though the reports are not alleged to be statistically significant.

PARTIES TO THE PROCEEDING

Petitioners are Matrixx Initiatives, Inc., Carl Johnson, William Hemelt, and Timothy Clarot, defendants-appellees below.

Respondents are James Siracusano, named plaintiff and appellant below, and the NECA-IBEW Pension Fund, lead plaintiff and appellant below, on behalf of themselves and all others similarly situated who purchased securities of Matrixx between October 22, 2003 and February 6, 2004.

RULE 29.6 DISCLOSURE

Matrixx Initiatives, Inc. has no parent corporation and no person or publicly-traded corporation owns more than 10% of Matrixx's stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

TABLE OF AUTHORITIES
(continued)

PETITION FOR A WRIT OF CERTIORARI

Petitioners respectfully seek a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The decision of the court of appeals is reported at 585 F.3d 1167 and is reprinted in the Appendix to the Petition ("App.") at 1a-34a. The district court's opinion is available at 2005 WL 3970117 and is reprinted at App. 35a-54a.

JURISDICTION

The court of appeals issued its decision on October 28, 2009, and denied a petition for rehearing and rehearing *en banc* on December 23, 2009. App. 55a-56a. The Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1254(1).

STATUTES AND REGULATION INVOLVED

The relevant statutory provisions of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and the Private Securities Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. §§ 78u-4(b)(2), and Securities and Exchange Commission (SEC) Rule 10b-5 are reproduced in the appendix. App. 57a-58a.

INTRODUCTION

This case presents a question of recurring importance under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 on which the courts of appeals are squarely divided: whether drug companies have a duty to disclose "adverse event" reports—i.e., reports by users of a drug that they experienced an ad-

verse event after using the drug—where the reports do not reflect statistically significant evidence that the adverse event may be caused by use of the drug. Three Circuits have held that drug companies have no duty to disclose adverse event reports until the reports provide statistically significant evidence that the adverse events may be caused by, and are not simply randomly associated with, a drug's use. Expressly disagreeing with those decisions, the court below rejected a statistical significance standard and allowed the case to proceed based on the failure to disclose adverse event reports that are not statistically significant.

That decision has immense consequences for pharmaceutical companies, investors, and consumers. The Food and Drug Administration receives hundreds of thousands of adverse event reports each year. Those reports are made without regard to whether there is any established relationship between use of a drug and an adverse event. Under the court of appeals' ruling, a pharmaceutical company that fails to disclose a small number of such complaints would be subject to suit under § 10(b) even though the complaints are not statistically significant and therefore do not indicate any causal relationship between use of the drug and the adverse event.

Faced with that rule, the only safe course for a company would be to provide investors with every adverse event report even though the company has no reason to believe that the report casts the slightest doubt on the safety of the drug. That result is not only harmful to reasonable investors, who depend on receiving significant rather than useless in-

formation. It is also detrimental to consumers. If drug companies disclose every adverse event report, the unfortunate result may be to deter confused consumers from using drugs that would be beneficial to their health.

As three courts of appeals have correctly concluded, a statistical significance standard is necessary to prevent these untoward consequences. The Court should therefore grant certiorari to resolve the conflict in the circuits on this issue and hold that adverse event reports can form the basis for a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 only when they are statistically significant.

STATEMENT OF THE CASE

1. Petitioner Matrixx Initiatives, Inc. is a pharmaceutical company that sells cold remedy products through its wholly-owned subsidiary, Zicam, LLC. App. 2a. One of Matrixx's main products is Zicam Cold Remedy (Zicam), which was produced in the form of a nasal spray or gel. Zicam's active ingredient is zinc gluconate. *See* App. 2a-3a, 4a.

On April 27, 2004, respondents brought suit on behalf of a putative class of investors who purchased Matrixx stock between October 22, 2003 and February 6, 2004. App. 4a. Respondents alleged that Matrixx and three of its executives (petitioners) violated § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 by failing to disclose material information regarding Zicam Cold Remedy. Specifically, respondents alleged that use of Zicam could cause "anosmia," or loss of the sense of smell. App. 3a.

In support of their conclusory allegation of a causal connection between Zicam and anosmia, respondents relied on allegations that, in a four-year period between 1999 and 2004, Matrixx received approximately 12 reports of user anosmia: one from Dr. Alan Hirsch, another from Dr. Miriam Linschoten, and ten from Dr. Bruce Jafek. *See* App. 25a. Respondents also alleged that, in the class period, Matrixx was named in four Zicam-related lawsuits, involving a total of nine plaintiffs, and in their briefing, respondents counted those plaintiffs as additional complainants. App. 25a-26a. It is not clear whether those plaintiffs actually represent additional adverse events.[1] Ultimately, however, the precise number of adverse event reports is beside the point. The critical point, for present purposes, is that respondents did not allege in their complaint that the small number of adverse event reports in the class period was statistically significant, much less allege facts that would raise an inference of statistical significance.

2. Petitioners filed a motion to dismiss respondents' complaint for failure to state a claim. The district court granted the motion. App. 35a-54a. The court invoked the Second Circuit's decision in *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000), as the standard for determining when allegations of undisclosed adverse event reports can satisfy the materiality requirement under § 10(b) and Rule 10b-5. As the district court ex-

[1] Respondents' complaint did not allege that the plaintiffs in the Zicam-related lawsuits were additional complainants, rather than simply a subset of the 12 individuals whose adverse events had already been reported to Matrixx.

plained, in *Carter-Wallace*, the Second Circuit held that no claim can be based on the nondisclosure of adverse event reports "unless such reports provide reliable statistically significant information that a drug is unsafe." App. 45a. Applying that standard, the district court concluded that respondents had alleged "no data as to the reliability and accuracy of the user complaints," and that "[e]ven if there were data as to the reliability" of the complaints, "12 user complaints is not statistically significant." App. 50a. The court therefore concluded that respondents failed to allege that the nondisclosure of the reports was a "material omission." *Id.*

The district court noted that the complaint alleged that by April 2004, after the class period had ended, there were 165 adverse event reports. App. 53a. It therefore allowed respondents to replead to cure the deficiency in the Complaint. But it warned that "[a]bsent allegations Defendants *knew* there was a definitive and statistically significant link between Zicam and anosmia *during the Class period* that was sufficiently serious and frequent to affect future earnings, any amendment would be futile." App. 54a (internal quotation marks omitted). The district court thereby used the statistical significance standard as a measure of both materiality and scienter.

3. The court of appeals reversed. The court recognized that "the [district] court relied on the statistical significance standard used by the Second Circuit in *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153, 157 (2d Cir. 1999), and *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000)." App. 23a. The court of appeals

"conclude[d], however, that the district court erred in relying on the statistical significance standard" to rule on materiality. *Id.* According to the court, "reliance on the statistical significance standard is inconsistent with the Supreme Court's rejection of bright-line rules and its emphasis on having materiality determined by the trier of fact." App. 34a.

The court then held that the respondents "sufficiently pled materiality" based on the nondisclosure of the adverse event reports, even though the reports were not alleged to be statistically significant. App. 34a. And based on the number and nature of the reports, the court further held that the inference that petitioners withheld the reports "intentionally or with deliberate recklessness is at least as compelling as any plausible nonculpable explanation." *Id.*[2]

REASONS FOR GRANTING THE PETITION

THE COURT SHOULD GRANT REVIEW TO DECIDE WHETHER A PLAINTIFF CAN STATE A CLAIM UNDER § 10(B) AND RULE 10B-5 BASED ON NONDISCLOSURE OF ADVERSE EVENT REPORTS THAT ARE NOT STATISTICALLY SIGNFICANT

The courts of appeals are divided on whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 based on a pharmaceutical company's failure to disclose adverse

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[2] While the appeal was pending in the Ninth Circuit, the FDA issued a warning letter, stating that some of the Zicam products "may pose a serious risk to consumers." App. 3a n.1. Because that warning letter was written more than five years after the close of the class period, it has no bearing on the question presented here.

event reports that are not statistically significant. That issue is an important and recurring one, not only for pharmaceutical companies and investors, but also for consumers who rely on the products those companies produce. This case presents an ideal vehicle for resolving that issue. And the court of appeals answered the question presented incorrectly. A plaintiff should be permitted to pursue a claim under § 10(b) based on nondisclosure of adverse event complaints only when those complaints are statistically significant. The Court should grant certiorari and reverse the judgment below.

A. The Courts of Appeals Are Divided on the Question Presented

The courts of appeals are divided on the question presented in this case. The First, Second, and Third Circuits have adopted a statistical significance standard for claims based on nondisclosure of adverse event reports, while the Ninth Circuit in this case expressly rejected a statistical significance standard.

1. a. *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153 (2d Cir. 1998) (*Carter-Wallace I*), is the seminal decision adopting the statistical significance standard. In an opinion by Judge Winter, the Second Circuit held that a drug company's failure to disclose adverse event reports could "not be[] materially misleading until [the company] had information that [the drug] had caused a statistically significant number of" adverse events. *Id.* at 157. The court explained that "[d]rug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be

caused by—rather than randomly associated with—use of the drugs." *Id.*

In *In re Carter-Wallace, Inc. Securities Litigation*, 220 F.3d 36 (2d Cir. 2000) (*Carter-Wallace II*), the Second Circuit reaffirmed that a claim under § 10(b) cannot be based on failure to disclose adverse event reports that are not statistically significant. In that case, the court of appeals explained that because adverse event reports to the FDA encompass any adverse event associated with a drug, "whether or not considered drug related," and because "[s]ome adverse events may be expected to occur randomly," such reports are not indicative of a "causal relationship" until they are "statistically significant." 220 F.3d at 41 (emphasis omitted). The court further held that nondisclosure of reports that are not statistically significant is not only "not materially misleading," but "any inference of scienter [is] negated as well." *Id.* Nor did it matter to the court that, after the class period ended, the drug was eventually linked to a series of deaths. The court explained that reports could not "relate back" in time and "reflect on Carter-Wallace's reasonable belief that the reports were random." *Id.* at 41. The Second Circuit continues to follow the statistical significance rule. *See Avon Pension Fund v. Glaxosmithkline PLC*, 343 F. App'x 671, 672-73 (2d Cir. 2009); *Masters v. Glaxosmithkline*, 271 F. App'x 46, 50 (2d Cir. 2008).

The Third Circuit has also adopted the statistical significance standard. In an opinion by then-Judge Alito, the Third Circuit held that "'drug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill ef-

fects may be caused by—rather than randomly associated with—use of the drugs.'" *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir. 2000) (quoting *Carter-Wallace I*, 150 F.3d at 157). Because the reports at issue were not "statistically significant," the court held that their nondisclosure was not "materially misleading." *Id.*

Similarly, the First Circuit has adopted the statistical significance test. In *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 48 (1st Cir. 2008), the First Circuit rejected a plaintiff's § 10(b) claim that was based on nondisclosure of adverse event reports. The court explained that there was "no basis to conclude that these results . . . were statistically significant," and that "'the receipt of an adverse report does not in and of itself show a causal relationship between [a drug] and the illness mentioned in the report.'" *Id.* at 50, 53 (quoting *Carter-Wallace II*, 220 F.3d at 41) (emphasis omitted).

b. In conflict with the decisions of those three circuits, the court of appeals in this case squarely rejected "the statistical significance standard used by the Second Circuit in *In re Carter-Wallace*." App. 23a. The court explained that, in its view, "the district court's reliance on the statistical significance standard to conclude that [respondents] failed to establish materiality [was] inconsistent with the Supreme Court's rejection of bright-line rules and its emphasis on having materiality determined by the trier of fact." App. 34a.

2. As a result of the Ninth Circuit's rejection of the statistical significance standard, the pleading

requirements for stating a securities claim against a pharmaceutical company depend entirely on the jurisdiction in which a plaintiff chooses to bring suit. Companies defending suits in the First, Second, and Third Circuits will be able to obtain prompt dismissals of claims based on adverse event reports lacking statistical significance. Companies forced to defend securities fraud suits in the Ninth Circuit, however, will be required to proceed past the pleadings stage, with all the costs and pressure to settle unmeritorious suits that entails. That difference in treatment of similarly situated companies is intolerable.

The conflict in the circuits is particularly alarming given the class-action nature of most § 10(b) actions. Any plaintiff who can establish jurisdiction in a district court within the Ninth Circuit could prevent application of the statistical significance standard to a nationwide class of investors. In effect, the Ninth Circuit's rule gives any class action plaintiff who can secure jurisdiction within the Ninth Circuit's wide geographic region a ready weapon to blunt the protection against unmeritorious suits offered by the First, Second, and Third Circuits. This Court should grant certiorari to resolve the conflict in the circuits and prevent the Ninth Circuit's rule from effectively becoming the law of the land without review by this Court.

B. The Question Presented Is a Recurring Issue of National Importance, and This Case Presents an Ideal Vehicle for Resolving That Issue

1. The question presented is a frequently recurring issue of national importance, deserving of a uni-

form national resolution. In 2008 alone, the FDA received a total of 526,527 adverse event reports for drugs and therapeutic biologic products. *See* U.S. Food and Drug Administration, Adverse Event Reporting System (AERS), Reports Received and Reports Entered into AERS by Year (2010), http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm. Under the court of appeals' approach, a small number of such reports, if undisclosed, could potentially form the basis for a lawsuit under § 10(b).

Plaintiffs are particularly likely to target the instances in which the FDA issues a warning letter or a recall. *See N.J. Carpenters*, 537 F.3d at 47. In fiscal year 2008, for example, the FDA's Center for Drug Evaluation and Research—the body responsible for regulating over-the-counter and prescription drugs—issued 379 product recalls and 87 warning letters. *See* U.S. Food and Drug Administration, *The Enforcement Story* 10-9, 10-16 (2009), http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129824.pdf. Under the court of appeals' standard, once such a letter or recall is issued, plaintiffs would have every incentive to sue based on nondisclosure of adverse event reports made at an earlier time, even if there were no statistically significant evidence of a causal link between the drug and the effect at that time. *See, e.g.*, *Carter-Wallace I*, 150 F.3d at 157 (no claim where adverse reports received before company acted were not statistically significant).

The effects of the Ninth Circuit's rejection of the statistical significance standard are profoundly un-

settling. The court's decision dramatically expands the number of investor suits against pharmaceutical companies that state a claim and substantially increases the pressure on companies to settle meritless claims.

The Court has previously granted review in similar circumstances. In *Dura Pharmaceuticals, Inc. v. Broudo*, the Court rejected a Ninth Circuit rule that "permit[ted] a plaintiff with a largely groundless claim to simply take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value, rather than a reasonably founded hope that the [discovery] process will reveal relevant evidence." 544 U.S. 336, 347 (2005) (internal quotation marks omitted); *see In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1298 (7th Cir. 1995) (Posner, C.J.) (recognizing the "intense pressure to settle" if a class is certified). The court of appeals' decision in this case has the same effect, forcing defendants to undergo discovery and the risk of class certification for claims that have no basis in medical reality.

To avoid these intolerable effects, a company's only safe alternative would be to provide investors with every adverse event report even though it has no reason to believe that the report casts the slightest doubt on the safety of the drug and even though it has no material significance to a reasonable investor. As the Court has recognized before, providing investors with such information "is hardly conducive to informed decisionmaking." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976).

Disclosing every adverse event report would also be detrimental to consumers. Because such information, no matter how carefully phrased, is likely to spawn confusion, the unfortunate effect would be to deter consumers from purchasing drugs that are needed to improve their health.

The resolution of the question presented in this case is therefore of great importance to pharmaceutical companies, investors, and consumers. For that reason, review of that question is clearly warranted.

2. This case also presents an ideal vehicle for resolving the question presented. In a four-year period in which Matrixx made countless sales of Zicam, respondents were able to identify 12 adverse event reports. Respondents did not allege in their complaint that the reports were statistically significant, nor did they allege facts that would support a plausible inference of statistical significance.

Application of the statistical significance standard therefore would result in dismissal of the complaint. Indeed, applying the statistical significance standard, the district court did precisely that. And while the court of appeals reversed that dismissal, it did so only because it rejected the statistical significance standard. This case therefore squarely presents the question whether a plaintiff can state a § 10(b) claim based on nondisclosure of adverse event reports that are not statistically significant.

C. The Court of Appeals Erred in Rejecting the Statistical Significance Standard

1. The Ninth Circuit erred in rejecting the statistical significance standard adopted by the First, Sec-

ond, and Third Circuits. This Court held in *Basic* that information is not material under the securities laws unless 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.'" *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988) (quoting *TSC Indus.*, 426 U.S. at 449). "The role of the materiality requirement" is to "filter out essentially useless information that a reasonable investor would not consider significant." *Id.* It is not to bury investors in an "avalanche of trivial information." *TSC Indus.*, 426 U.S. at 448.

The statistical significance standard properly implements that materiality requirement. When adverse event reports are not statistically significant, they fail to provide any indication that the effects "may be caused by . . . use of the drugs." *Carter-Wallace I*, 150 F.3d at 157. Instead, they indicate no more than a random relationship between use of the drug and the effect. *Id.* Accordingly, as the courts that have adopted the statistical significance standard have concluded, such reports are not material: they would not be viewed by reasonable investor as "significantly altering the 'total mix' of information made available." *Basic*, 485 U.S. at 231-32.

2. The Ninth Circuit rejected the statistical significance requirement because it believed that any "bright-line rule" for materiality is inconsistent with *Basic*. App. 34a But the Court in *Basic* rejected the bright-line rule proposed in that case because it was based on policy considerations that were not tied to "the significance of the information upon the investor's decision." 485 U.S. at 234. The statistical sig-

nificance standard, by contrast, is directly tied to the significance of adverse event reports to a reasonable investor. As noted above, the statistical significance standard captures the common sense insight that no reasonable investor would be likely to deem important reports of adverse events that are not statistically significant.

In *Jackvony v. RIHT Financial Corp.*, 873 F.2d 411, 415 (1st Cir. 1989), the First Circuit, in a post-*Basic* case, similarly adopted a bright-line rule that was directly tied to the importance of the information to a reasonable investor. In an opinion by then-Judge Breyer, the First Circuit held that internal discussion regarding a merger feeler from another company that precedes any merger negotiations is categorically non-material. The court explained that "[a]ny reasonably sophisticated investor in securities buying shares in a large corporation would expect that, from time to time, other corporations might express an interest in buying, or that the large corporation's directors might discuss what it should do if it obtains such offers." *Id.* The court added that "[f]or large corporations to make public announcements every time directors discuss any such matter in terms as vague as those presented in this evidence or receive 'tentative feelers' of the general sort revealed by th[e] evidence [before the court] . . . would more likely confuse, than inform, the marketplace." *Id.*

The same kind of analysis applies here. Any reasonably sophisticated investor buying shares in a pharmaceutical company must realize that consumers will, from time to time, experience adverse events after using the company's product. *Carter-*

Wallace II, 220 F.3d at 41. "Some adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill." *Id.* Consequently, until adverse reports suggest "the ill effects may be caused by—rather than randomly associated with—use of the drug[]," no reasonable investor would likely deem that information material. *Carter-Wallace I*, 150 F.3d at 157. Requiring disclosure of every adverse report, as the court of appeals effectively did below, "would more likely confuse, than inform, the marketplace." *Jackvony*, 873 F.2d at 415. The court of appeals therefore erred in rejecting the statistical significance standard.

3. In addition, application of a statistical significance requirement is necessary to comport with the PSLRA's requirement that plaintiffs "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). This Court in *Tellabs* held that, "[t]o qualify as 'strong' within the intendment of § 21D(b)(2) . . . an inference of scienter must be more than merely plausible or reasonable—it must be 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).

Where adverse event reports are not statistically significant, the inference of fraudulent intent is not "at least as compelling as any opposing inference of nonfraudulent intent." *Id.* Instead, the more compelling inference is that defendants did not disclose information that was not statistically significant because it was medically meaningless. Thus, as the Second Circuit held in *Carter-Wallace II*, nondisclo-

sure of reports that are not statistically significant is not only "not materially misleading," but "any inference of scienter [is] negated as well." 220 F.3d at 41. For that reason as well, the court of appeals erred in rejecting the statistical significance standard. To resolve the conflict in the circuits on this issue of recurring importance and to correct the error by the court below, this Court's review is warranted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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March 23, 2010

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