No. 09-1156

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

REPLY BRIEF FOR PETITIONERS

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The courts of appeals are squarely divided on the question whether § 10(b) of the Securities Exchange Act of 1934 requires drug companies to disclose adverse event reports that do not reflect statistically significant evidence that an adverse event may be caused by, rather than randomly associated with, use of a drug. Respondents do not deny that this question is one of recurring, national importance. Pet. 10-13.

Respondents instead oppose review on essentially three grounds. First, they contend that circuits are not in conflict over the question presented. Opp. 13-16. Their position misconstrues both the decision below and the other circuit decisions with which it conflicts.

Second, respondents argue that the case is a poor vehicle for addressing the question presented. They contend the case involves "unique" facts because petitioners received "specific, identical complaints" of the same adverse event. Opp. 18 (emphasis omitted). But *exactly the same is true* of the conflicting circuit decisions. What produced different outcomes was the legal standard applied by the circuits, not differences in the consumer complaints alleged. Respondents' further suggestion that they would prevail even under the correct legal standard is wrong. The district court found no statistical significance, and the court of appeals did not disturb that finding. Even now, respondents make no plausible claim of statistical significance.

Finally, respondents argue that the Ninth Circuit's decision is correct, which is irrelevant to whether certiorari should be granted, and wrong as

well. The statistical significance standard is faithful to *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), and necessary to evaluate whether a plaintiff has stated facts that give rise to a "strong inference" of scienter as required by *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

The petition should be granted.

A. The Circuits Are In Conflict

Respondents erroneously contend that the conflict described in the petition is "illusory." Opp. 13. The Ninth Circuit below squarely rejected the statistical significance standard adopted by the First, Second, and Third Circuits for analyzing securities fraud claims based on nondisclosure of adverse event reports.

1. Respondents assert that two of the circuit precedents require statistical significance only with respect to scienter, and that the decision below is limited to materiality. Opp. 13-14 (citing *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35 (1st Cir. 2008); *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36 (2d Cir. 2000) (*Carter-Wallace II*)). This is wrong in two respects.

First, the district court in this case relied on the statistical significance standard as a measure of *both* materiality and scienter, Pet. 5; Pet. App. 45a, 54a, and the Ninth Circuit reversed the district court's dismissal on both counts, Pet. App. 34a. The decision below thus conflicts directly with the holdings in the First and Second Circuits that statistical significance is necessary to establish scienter.

Second, contrary to respondents' submission, the Second Circuit clearly requires statistical signifi-

cance *for materiality*. In the *first Carter-Wallace* decision—the seminal decision adopting the statistical significance standard—the Second Circuit expressly applied the standard to the materiality element: "The [positive] statements in Carter-Wallace's Form 10-K and its 'Report to Shareholders' did not become *materially misleading* until Carter-Wallace had information that [the drug] had caused a statistically significant number of deaths." *In re Carter-Wallace, Inc. Securities Litigation*, 150 F.3d 153, 157 (2d Cir. 1998) (emphasis added). Multiple subsequent Second Circuit decisions have applied *Carter-Wallace I* to require statistical significance for materiality. Pet. 7-8 (citing cases). Respondents inexplicably ignore *Carter-Wallace I* and its progeny.

Respondents instead discuss only the *second* decision in *Carter-Wallace*, which they say was limited to scienter. Respondents misconstrue the decision. *Carter-Wallace II* first confirms the *materiality* analysis of *Carter-Wallace I*, reiterating the prior decision's holding that a company's positive "financial statements [are] not materially misleading" unless there is a statistically significant link between the product and reported adverse events. 220 F.3d at 41. *Carter-Wallace II* then simply *extends* the statistical significance already required for materiality to scienter as well. *Id.* at 39. As the decision explains, "awareness of medical reports that could . . . be[] random cannot lead to the conclusion that [a company] was reckless" in promoting a product. *Id.* at 42 (quotation omitted).

The Second Circuit's decision in *Ganino v. Citizens Utilities Co.*, 228 F.3d 154 (2d Cir. 2000), does not, as respondents suggest, negate the materiality rulings in the *Carter-Wallace* decisions. *Ganino*

postdates those decisions, so it could not overrule them even if it were to the contrary. *See United States v. Wilkerson*, 361 F.3d 717, 732 (2d Cir. 2004) (panel cannot overrule prior panel ruling). But *Ganino* plainly is *not* to the contrary: the court there *did not even consider statistical significance.*[1] Its irrelevance is confirmed by subsequent Second Circuit decisions affirming the dismissal, on materiality grounds, of cases in which plaintiffs failed to allege statistically significant adverse event reports. Pet. 7-8. The *Carter-Wallace* rule requiring statistical significance clearly continues to control in the Second Circuit—in direct conflict with the Ninth Circuit's decision in this case.[2]

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[1] The issue in *Ganino* was whether the failure to disclose the source of certain income was immaterial as a matter of law where that income was only 1.7% of relevant revenues, and thus arguably within the "standard practice in corporate America" not to disclose a "charge or event" unless it is likely to "affect [the] company's earnings, positively or negatively, by 3% to 10%." 228 F.3d at 161. The court of appeals reaffirmed that "[a]n omitted fact may be immaterial if the information is trivial," but refused to permit materiality under those circumstances to turn on "[m]agnitude by itself, without regard to the nature of the [undisclosed] item." *Id.* at 162 (quotation omitted). The proper approach, the court explained, was to consider what the omitted figure meant. For example, the court could consider whether a misstated figure "masks a change in earnings or other trends," or "hides a failure to meet analysts' consensus expectations for the enterprise." *Id.* at 163 (quotation omitted). *Ganino* is thus entirely consistent with the statistical significance standard, which does not turn on a raw number of adverse event reports ("magnitude") but rather considers what those reports mean—whether they suggest a causal connection between product and event or reflect only random chance.

[2] Respondents also cite decisions from the Third, Fifth, and Seventh Circuits that ostensibly "comport[] with" the Ninth Circuit's rejection of the statistical significance standard. Opp.

2. Though respondents err in describing the Second Circuit's statistical significance requirement as limited to scienter, they correctly concede that the Third Circuit's decision in *Oran v. Stafford*, 226 F.3d 275, 283-84 (3d Cir. 2000), addressed statistical significance "in connection with materiality." Opp. 14. Respondents nevertheless contend that *Oran* can be ignored because then-Judge Alito's opinion "misunderstood" *Carter-Wallace*. Opp. 15. But respondents' disagreement with *Oran*'s materiality holding does not change the fact that *Oran* is binding in the Third Circuit and squarely conflicts with the decision below. In any event, as just shown, *Oran* accurately reads *Carter-Wallace I* as adopting a statistical significance requirement for purposes of materiality. The Third Circuit thus made no error in expressly following *Carter-Wallace* to hold 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 effects may be caused by—rather than randomly associated with—use of the drugs,'" because reports that are not statistically significant are not material. 226 F.3d at 284 (quoting *Carter-Wallace I*, 150 F.3d at 157).

There also is no merit to respondents' suggestion that "*Oran*'s materiality holding turned primarily on the lack of stock-price movement there in connection with allegedly material disclosures." Opp. 14. The claims in *Oran* were premised on multiple omissions, and the court rested its holding on stock price only

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15-16. Those cases, however, do not even consider the statistical significance standard, and general references to *Basic*'s materiality rule do not constitute rejection of that standard, which is perfectly consistent with *Basic*, as explained *infra* at 9-11.

with respect to what was known as "the Mayo data." 226 F.3d at 283. The court in no way relied on stock price in evaluating the "European data and the adverse reaction reports." *Id.* at 284. The court held that information immaterial solely because it was not statistically significant. *See id.* at 283-84. That holding, like the holding in *Carter-Wallace* that it followed, cannot be reconciled with the Ninth Circuit's decision below.[3]

B. This Case Is A Good Vehicle For Review

Respondents cannot deny that the Ninth Circuit expressly rejected "the statistical significance standard used by the Second Circuit in *In re Carter-Wallace*" and held without qualification that "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." Pet. App. 23a, 34a. And respondents affirmatively concede that the validity of the statistical significance standard is squarely presented by this case. Opp. i (stating that a question presented by this case is whether the Ninth Circuit "correctly held that the district court's reliance upon a singular 'statistical significance' standard in order to assess . . . materiality" was in error); *id.* at 11 (observing that, "[f]aced with a district-court decision requiring that the 'materiality' element of a securities-fraud claim be supported by 'statistically

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[3] Even assuming that *Oran*'s "primary" holding turned on stock price, and the court's adoption of the statistical significance standard were an alternative holding, that holding would still be binding, and the conflict would remain. *See United States ex rel. Caruso v. Zelinsky*, 689 F.2d 435, 440 (3d Cir. 1982) ("an alternate holding has the same force as a single holding; it is binding precedent").

significant' information, the Ninth Circuit . . . reject[ed] that bright-line approach").

Respondents nevertheless contend that certiorari is inappropriate because the decision below is limited to "unique" facts. Opp. 17-18. It is not. Respondents assert that the adverse event reports "concerned a singular, dramatic reaction" and thus presented "specific, identical complaints" that differ from the "broad randomness of typical adverse-event reports" in other cases. Opp. 17-18 (emphasis omitted). In fact, *every other case* applying the statistical significance standard has involved exactly the same kind of "specific, identical complaints" of a single dramatic reaction—indeed, of life-threatening conditions far more severe than anosmia. In *Carter-Wallace*, the company received "information . . . indicating that [its drug] caused, in some patients, a fatal form of acquired bone-marrow failure known as aplastic anemia." *Carter-Wallace I*, 150 F.3d at 155. In *Oran*, the company "knew of at least 31 cases of heart valve abnormalities in European diet-pill users." 226 F.3d at 279. In *New Jersey Carpenters*, the cited clinical trials involved four deaths from opportunistic infections. 537 F.3d at 50.

The facts of this case thus fall well within the norm for statistical significance cases. Indeed, the question of statistical significance arises in these cases precisely *because* there are multiple reports of the same adverse event allegedly associated with use of a certain drug. The question in such cases is whether those reports suggest that "ill effects may be caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings." *Carter-Wallace I*, 150 F.3d at 157. This case thus poses ex-

actly the same problem presented by other statistical significance cases—the only difference is the one difference that matters: the Ninth Circuit applied a different legal standard and thereby reached the opposite result.

Respondents also suggest that review should be denied because their complaint would survive dismissal even under the legal standard applied in other circuits. Not so: the complaint did not allege statistical significance; the district court concluded that the incident reports were not statistically significant; and respondents did not amend their complaint to allege statistical significance, even after the district court offered them the opportunity to do so (Pet. App. 53a-54a). Nor did the Ninth Circuit suggest in any way that the complaint could survive the statistical significance standard—to the contrary, the court resurrected the complaint only by rejecting the statistical significance standard as a matter of law. The validity of that legal ruling is squarely at issue here.

In any event, respondents' complaint clearly would not pass muster under the correct standard. Respondents emphasize that what they count to be 23 adverse event reports are "more than *double* the 10 adverse events deemed significant in *Carter-Wallace*." Opp. 20.[4] As respondents' opposition itself

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[4] Respondents miscalculate the number of relevant reports. The complaint does not, as they assert, "tabulate[]" the reports received during the class period. Opp. 23. In addition, the complaint does not allege that the nine plaintiffs in Zicam-related lawsuits were additional complainants, rather than a subset of the 12 individuals whose events had already been reported to Matrixx. Pet. 4 & n.1. In any event, the precise number of reports is for present purposes irrelevant—

acknowledges, however, statistical significance is not measured by the raw number of adverse event reports a company receives. The number of reports must be evaluated in light of various other factors, including the sample size from which the reports are taken. Opp. 19 (citing article recognizing importance of "sample size" for statistical significance). In *Carter-Wallace I*, the drug company itself conceded based on a study conducted in coordination with the FDA that 10 adverse incident reports of its prescription drug provided statistically significant evidence of a causal connection where the company received those reports in a seven-month period, and the last four complaints were received in one month. 150 F.3d at 154-55, 157.

In this case, by contrast, respondents point to only a small number of complaints received over the course of five years for an over-the-counter product for which millions of units have been sold. *See generally* Matrixx Initiatives, Inc., Form 10-K Annual Report (Mar. 28, 2003) (Zicam Cold Remedy accounted for more than 70% of 2002 net sales of $23.5 million). There can be no plausible allegation that the minuscule number of reports received, compared to millions of products sold over five years, was statistically significant.

C. The Decision Below Is Incorrect

Respondents finally contend that the Ninth Circuit's decision is correct. Those merits arguments are just that—merits arguments, not reasons to deny certiorari. And they are wrong in any event.

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respondents have failed to allege statistically significant reports by anyone's calculation. *Id.*

1. The statistical significance standard is not contrary to *Basic*. Opp. 11-13. *Basic* holds that information is not material 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." 485 U.S. at 231-32. Application of the statistical significance standard not only comports with *Basic*, it is actually compelled by *Basic*'s rule: one cannot determine "whether a reasonable shareholder would consider it important" that a number of "Zicam users had lost their sense of smell" (Opp. 12 (quotation omitted)) without knowing whether that number suggests a "causal connection between [drug] and [event]" or rather a "random and statistically insignificant" response that "may be expected to occur" with any drug, particularly "a drug designed to treat people that are already ill." *Carter-Wallace II*, 220 F.3d at 40, 41; *see Jackvony v. RIHT Fin. Corp.*, 873 F.2d 411, 415 (1st Cir. 1989) (Breyer, J.) (citing *Basic* in holding that internal discussion regarding merger feeler preceding any negotiations is categorically non-material because "[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").

The statistical significance inquiry thus is not the type of "bright-line" rule the Court declined to adopt in *Basic*. In *Basic*, the Court rejected a rule that made materiality turn on the existence of a "single fact or occurrence" that was not tied to "the significance of [that] information upon the investor's deci-

sion." 485 U.S. at 234, 236. The statistical significance standard, by contrast, is directly tied to the significance of the information to an investor's decision. And it operates to determine whether multiple potentially relevant facts—i.e., adverse event reports—could possibly have sufficient clinical meaning to be significant to a reasonable investor.

2. Application of a statistical significance standard is also necessary to satisfy the requirement that plaintiffs plead with particularly facts giving rise to a "strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2). Where adverse event reports are not statistically significant, the inference that nondisclosure of such reports was motivated by fraudulent intent simply is not "at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314. The much more compelling inference is that the reports were not disclosed simply because no appropriate medical or scientific inferences could be drawn from them. Pet. 16-17.

Respondents insist that an inference of medical non-significance does not "comport[] with the record" of this case. Opp. 22. As explained above, however, nothing in the record suggests that the non-disclosed reports reflected any statistically valid inference that Zicam use caused the reported events. And contrary to the Ninth Circuit's decision, "[w]ithholding reports of adverse effects" cannot reasonably be deemed "an extreme departure from the standards of ordinary care" (Pet. App. 33a (quotation omitted)) where those reports do not establish any statistically significant relationship between product and adverse event. *See Carter-Wallace II*, 220 F.3d at 42 ("Carter-Wallace's awareness of medical reports that could have been random cannot lead to the conclu-

sion that Carter-Wallace was reckless in permitting the advertisements to continue."). In short, it is impossible to find a strong inference of scienter on the basis of adverse event reports that are statistically meaningless. The Ninth Circuit's decision to the contrary is wrong.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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